AMENDMENT NO. 2

No. BPPI/SURGICAL/RC-097/2019 Dated: 05.04.2019

Subject: Tender No. BPPI/SURGICAL/RC-097/2019 dated 14th March 2019 for supply of Surgical Consumables to Bureau of Pharma Public Sector Undertaking of India (BPPI).

Reference: Pre-Bid meeting held on 26th March 2019 at 11 A.M in the premises of BPPI.

The following amendment in Tender Document is hereby authorised:

PART-A

S No.	Tender Clause/Reference	Query/Suggestion	Amendment
1	Clause No. 1(i)	Bidders have requested to extend the due date of tender opening date.	Tender opening date has been extended up to 11.04.2019 in Amendment 1.
2	Clause no. 2(a)(i) &(ii)	(i) Bidder has requested to allow importers/ distributors to participate in tender. (ii) Some bidders have requested to clarify for the eligibility of items - Digital thermometers, Nebulizer, Glucometer and Digital BP instrument which are manufactured in India by assembling the imported parts of the device.	(i)Tender condition prevails. **(ii) For I**tems – Digital thermometers Nebulizer, Glucometer and Digital BP instrument; bidders assembling above final product will be considered with the valid license as per Clause no. 2.
3	Clause no. 2(b)(ii) I	(ii) To relax Annual average, turn over Rs. 2 crores of last 3 years for MSME suppliers.	Tender condition prevails.
4	Clause no.2 (h) after clause no 2 (d)	Clarification about clause no. 2 (h)	Clause no 2(h) after clause no 2(d) is hereby amended as **clause no 2 (e)**
5	Claus no. 2 (i)	Bidders asked clarification whether registration certificate of GS1 India for barcoding may be submitted later.	Tender condition prevails.
6	Note (1) under Clause no. 2 (Eligibility Criteria)	Clarification about 7002 (Clinical Thermometer).	**"and 7002 (Clinical Thermometer)"** is hereby **deleted** from Note (1) under Clause no. 2 (Eligibility Criteria).

7	Clause no. 2 (Eligibility Criteria)	Bidders requested to allow exemption of turn over and prior experience for start-up companies.	Add the following clause after Note (1) under Clause no. 2 (Eligibility Criteria): - **2) The prior turnover and prior experience for Start-ups (as defined by Department of Industrial Policy and Promotion) shall not be applicable subject to submission of certificate of recognition as start-up by Department of Industrial Policy and Promotion for quoted item.**
8	Clause no. 2(c), 4.1(j) and S.no. 12 of Annexure VI (checklist)	Bidder has requested to accept the Non-Conviction Certificate issued within one year and accept **AFFIDAVIT** from the bidder that they have not been convicted.	Tender condition prevails. Bidders need to submit valid Non-Conviction certificate issued by licensing authority. In case, certificate is older than 6 months, the bidders are required to submit fresh Non -conviction certificate not older than 6 months within 15days of Technical bid opening date failing which their bid shall be rejected.
9	Clause 3 (ii)	Clarification for Annexure V	**Annexure V** is hereby amended as **Annexure IV.**
10	Clause 3 (ii), 7.1 & SNo.2 of Annexure VI (Check List)	To exempt the EMD for MSME suppliers.	Tender condition prevails as such provisions applicable to MSME's are already included in tender document.
11	Clause no. 3 (ix) & 9.1 (i)	Bidders have requested to award at least 50% quantity to L1 bidder instead of 30% quantity.	Tender condition prevails.
12	Clause 4.1 (g)	Clarification about supplies as per packing and labelling by foreign manufacturer.	**FOR: -** MSC issued under brand name or under generic name (by the state licensing authority) will also be accepted but **supplies will be accepted as**

			per packing and label by foreign manufacturer in their brand subject to affixing sticker for Logo as approved by BPPI & BPPI MRP. **READ: -** MSC issued under brand name or under generic name (by the state licensing authority) will also be accepted.
13	Clause 4.1 (o)	Bidders have informed that it is difficult to prepare small no. of samples as per tender specification. However, they will supply the item as per tender specification after award of contract. They also desired whether 3 units or 3 pack size sample is required.	ADD the following after Clause 4.1 (o): - **Bidders are required to submit 3 units of trade sample of each quoted item which are being supplied in the market.**
14	Clause no. 10.1	Bank guarantee @5% value of each purchase order may be allowed.	Tender condition prevails.
15	Clause no. 12.4(a) &12.4(b)	(i) One of the bidders has requested to increase the delivery period from 45 days to 75 days for first order and for subsequent orders, the delivery period from 30 days to 45 days. (ii) Another bidder has requested to increase the delivery period from 45 days to 60 days for first order and for subsequent orders, the delivery period from 30 days to 45 days.	Tender condition prevails.

16	Clause no.16	Suppliers requested that payment period should be reduced from 90 days and payment should be made invoice/ bill wise without any restriction to supply the minimum 50% of quantity ordered for the items in Purchase order.	Tender condition prevails.
17	Clause no.17	Supplier requested to reduce or delete 1.5% handling and testing charges.	Tender condition prevails.
18	Clause no. 23(i)	Clarification about the disposal of appeal.	Clause no. 23(i) may read as under instead of existing clause: **Any Tenderer aggrieved by the order passed by the Tender Accepting Authority under section 10 of the said Act, may appeal to the Chairman, BPPI within ten days from the date of receipt of order and the Chairman, BPPI shall dispose the appeal within fifteen days from the date of receipt of such appeal**.
19	Annexure I (BARCODE REQUIREMENTS)	Clarification about the code on GS1 application.	**FOR: -** Mandatory Mapping of Manufacturer's GTIN with BPPI **Drug** Code on GS1 application. **READ: -** Mandatory Mapping of Manufacturer's GTIN with BPPI **Item** Code on GS1 application.
20	Annexure V	Clarification about date, seal, signature of Auditor/Chartered Accountant.	**The date, seal, signature of Auditor/Chartered Accountant** is **deleted** mentioned after **NOTE**.
21	Annexure VI (Check List)	Clarification about S No.3, 21 &24	S No.3, 21 &24 are hereby deleted as same document have been mentioned under S No.5, 22 &25 respectively.

PART B

S.no.	Tender Clause/ Reference No.	Item Code & Item Specification, unit size, packing.	Query	Amendment
1.	Annexure VIII, IX, BOQ and Clause 8.1 (vii)	Item Code 8110 ADULT DIAPER (SMALL SIZE)	Clarification about the specification.	**FOR: -** ADULT DIAPER (SMALL SIZE) **READ: -** BABY DIAPER (SMALL SIZE)
2.	Annexure VIII, IX, BOQ and Clause 8.1 (vii)	Item Code 5037: Sterile Disposable (Single Use) Teflon/ PTFE I.V. Cannula with Integrated 3-Way stop Cock. Size 26G), Should be pack in Transparent, single blister pack.	Clarification about the specification.	The specification is hereby amended as: **Sterile Disposable (Single Use) Teflon/ PTFE I.V. Cannula** with X - Ray Opaque Line, wings and injection port. Size 26G, should be pack in Transparent, single blister pack. Should conform to IS 10555 Standard
3.	Annexure VIII, IX, BOQ and Clause 8.1 (vii)	**Item Code 5077**: Rapid Diagnostic Malaria Test Kit Test card; Sterile lancet, Reagents including buffer solution in a dropping bottle. The test kit should be able to rapidly diagnose both P. falciparum and P. vivax The product should comply with ISO 9001 ISO 13485 The invalid rate should be less than 5% should have space for recording particulars of test. US-FDA approved	Clarification about the specification	The specification is hereby amended as: - **Rapid Diagnostic Malaria Test Kit** Test card; Sterile lancet, Reagents including buffer solution in a dropping bottle. The test kit should be able to rapidly diagnose both P. falciparum and P. vivax The product should comply with ISO 9001 & ISO 13485 (QMS) The invalid rate should be less than 5% Should have space for recording particulars of test.

4.	Annexure VIII, IX, BOQ and Clause 8.1 (vii)	**Item Code 5078:** Dengue Antigen IgG/IgM AB Test Kit (Uses serum, plasma or whole blood Detects all four Dengue serotypes (DEN 1, 2, 3, 4) Result time: 5 minutes Sensitivity: IgM - 96.5-99.5, IgG- 95.6-98.6 Specificity: IgM - 97-100%, IgG - 97-100 Shelf life 24 months Storage 2- 30 degree Celsius	Clarification about the specification	The specification is hereby amended as: - **Dengue NS1 Ag + Ab Combo Kit** (Uses whole blood serum or plasma) Detects all four Dengue serotypes (DEN 1, 2, 3, 4) Result time: 10-15 minutes Sensitivity: IgM - 96.5-99.5, IgG- 95.6-98.6 Ag – 92-95% Specificity: IgM - 97-100%, IgG - 97-100, Ag – 98-100% Shelf life 24 months Storage 2- 30°C.
5.	Annexure VIII, IX, BOQ and Clause 8.1 (vii)	**Item Code 6030**: Sterile Disposable Perfusion set with airway and needle adult use 150cm long smooth kink resist	Clarification about the specification and packing.	The specification is hereby amended as (i) Sterile Disposable Perfusion set with air vent for gravity infusions and pressure infusions; Drop formation; 20 drops = 1ml ± 0.1 ml Soft, clear PVC tubing, DEHP free plasticizer with superior, well documented safety properties. For adult use; 150cm long smooth kink resistant. *(ii)* ***Packing has been amended to 25pcs in mono pack instead of 10 in a box followed by maximum 200 units in shipper pack.***
6.	Annexure VIII, IX, BOQ and Clause 8.1 (vii)	**Item Code 6031**: Sterile Disposable Perfusion Set (Infusion set) with Built Airway and Needle (Adult Use). Burette type measured volume chamber of 100 ml Drop size of approx. 60 drops per ml Injection port, latex free, for intermittent medication. Floating auto shut off valve (latex free) in burette. Soft and kink resistant PVC tubing. Roller controller for flow control	Clarification about the specification and packing	The specification is hereby amended as: - Sterile Disposable Perfusion Set (Infusion set) with Built Airway and Needle (Adult Use). Burette type measured volume chamber of 150 ml Drop size of approx. 60 drops

		Tube length 150 cm, 23G needle, Should conform to IS No.12655 (part-4 of 2003) As per Drugs and Cosmetics Act 1940.		per ml; Injection port, latex free, for intermittent medication. Floating auto shut off valve (latex free) in burette. Soft and kink resistant PVC tubing. Roller controller for flow control Tube length 150 cm; 23G needle, Should conform to IS No.12655 (part-4 of 2003) As per Drugs and Cosmetics Act 1940.
7.	Annexure VIII, IX, BOQ and Clause 8.1 (vii)	**Item Code 6035: Sterile Disposable (Single Use) Teflon/ PTFE I.V. Cannula** with integrated 3 Way stop cock. Size 18G, should be pack in Transparent, single blister pack. Should conform to IS 10555 Standard	Clarification about the specification	The specification is hereby amended as: **Sterile Disposable (Single Use) Teflon/ PTFE I.V. Cannula** with X - Ray Opaque Line, wings and injection port. Size 18G, should be pack in Transparent, single blister pack. Should conform to IS 10555 Standard.
8.	Annexure VIII, IX, BOQ and Clause 8.1 (vii)	**Item Code 6036: Sterile Disposable (Single Use) Teflon/ PTFE I.V. Cannula** with Integrated 3-Way stop Cock. Size 20G, should be pack in Transparent, single blister pack. Should conform to IS 10555 Standard	Clarification about the specification	The specification is hereby amended as **Sterile Disposable (Single Use) Teflon/ PTFE I.V. Cannula with X - Ray Opaque Line, wings and injection port**. Size 20G, should be pack in Transparent, single blister pack. Should conform to IS 10555 Standard
9.	Annexure VIII, IX, BOQ and Clause 8.1 (vii)	**Item Code 6037: Sterile Disposable (Single Use) Teflon/ PTFE I.V. Cannula** with Integrated 3-Way stop Cock. Size 22G), Should be pack in Transparent, single blister pack. Should conform to IS 10555 Standard	Clarification about the specification	The specification is hereby amended as **Sterile Disposable (Single Use) Teflon/ PTFE I.V. Cannula with X - Ray Opaque Line, wings and injection port**. Size 22G, should be pack in Transparent, single blister pack. Should conform to IS 10555 Standard

10.	Annexure VIII, IX, BOQ and Clause 8.1 (vii)	**Item Code 6038: Sterile Disposable (Single Use) Teflon/ PTFE I.V.** Cannula with Integrated 3-Way stop Cock. Size 24G), Should be pack in Transparent, single blister pack. Should conform to IS 10555 Standard	Clarification about the specification and packing	The specification is hereby amended as **Sterile Disposable (Single Use) Teflon/ PTFE I.V. Cannula with X - Ray Opaque Line, wings and injection port**. Size 24G, should be pack in Transparent, single blister pack. Should conform to IS 10555 Standard
11.	Annexure VIII, IX, BOQ and Clause 8.1 (vii)	**Item Code 8120:** Lancets Round Sterile tip Onetime use; 32G, in virgin packing Length: 30mm ± 2mm Compatibility: Should be compatible with Janaushadhi glucometer.	Clarification about the specification	The specification is hereby amended as: - Lancets Round Sterile tip Onetime use; 28G, in virgin packing Length: 30mm ± 2mm Compatibility: Should be compatible with Janaushadhi glucometer.
12.	Annexure VIII, IX, BOQ and Clause 8.1 (vii)	**Item Code 8121:** Glucometer Test Strip	Clarification about the specification	The specification is hereby amended as: - Glucometer Test Strip (Compatible with Janaushadhi Glucometer Digital)
13.	Annexure VIII, IX, BOQ and Clause 8.1 (vii)	Item Code 8122: GLUCOMETER DIGITAL (1 glucometer- 25 strips, 15 lancets,1 lancing device,1battery 3v. Warranty card)	Clarification about the specification	The specification is hereby amended as: - **GLUCOMETER DIGITAL (1 glucometer- 25 strips, 25 lancets,1 lancing device,1battery 3v. Warranty card)** **Glucometer Specification:** Glucose ranges : 30 - 800 md/dL Analysis time : 5 Sec Sample Volume : < 1.0 micro-litres Sample : Whole Blood Fill detection : Automatic Battery (Replaceable) : 3v Lithium Battery (CR2032), should work for minimum 1000 test Minimum memory : 50 samples (Erasable)

				Replacement Warranty Period : 3 Years Storage Temp. : 0-50°C Operating Temp. : 2-50°C Relative Humidity : 10-95% (Non Condensing) Code : No Coding Strip Ejector facility to avoid contamination with blood. ISO 13485 (QMS) **Note**: 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.
14.	Annexure VIII	Item Code 8136 Electrical Nebulizer Machine		Annexure VIII (E) for Item Code 8136 – Jan Aushadhi Nebulizer The Medication Cup Capacity is hereby amended as 5-10ml (cc).

NOTE: - (i**)** All the Medical devices and Diagnostic kits should be provided with **Instruction Manual**.

(ii) Bidders need to supply the product with COA (Certificate of Analysis) & STP (Standard Testing Procedure) at the time of delivery of the product to Central Warehouse (CWH) of BPPI.

Part-C: - **Important Instructions to Fill the BOQ (Price Bid) with the help of WPS office.**

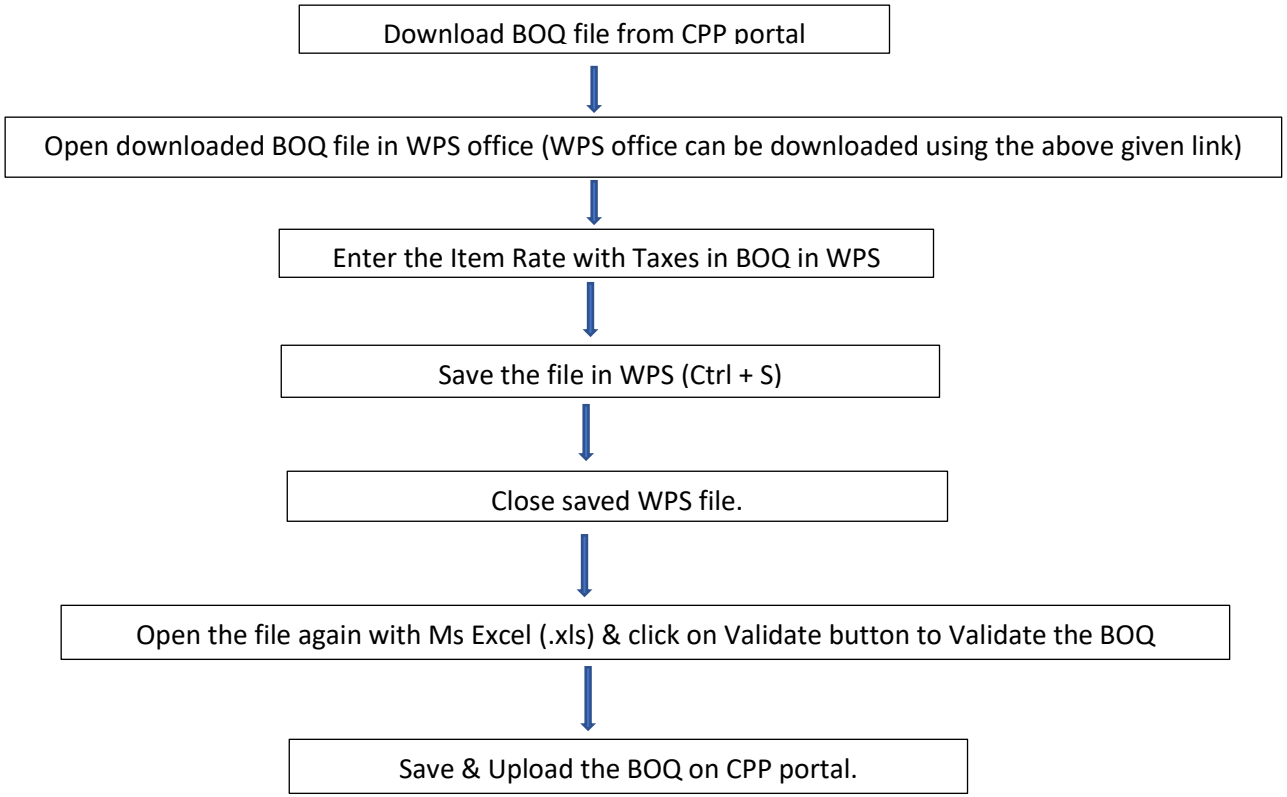
The following instructions for filling and uploading of BOQ on CPP Portal is hereby authorized: -

(i) In case the BOQ for the price bid of the tender in not able to be opened with Excel, kindly download it in WPS Office.

NOTE: To download the WPS Office, link is given as under for support:

https://www.wps.com/

FLOW CHART FOR FILLING & UPLOADING OF BOQ (Post upgradation of CPP Portal): -



NOTE: Whenever Run-time error "1004" pop-up message will come, kindly click on end button to proceed further.

(ii) ***For any other assistance regarding filling of tender you may call the under signed:***

(a) CPPP Help Line No.

Ph: 0120-4001002, 0120-4001005

(b) Manoj Sharma

Executive (IT & Analytics)

Ph: 011- 49431815

(c) P. K. Thakur

Executive (Procurement)

Ph: 011- 49431829

(d) Manik Bera

Dy. Manager (Procurement)

Ph: 011-49431854

Sd/-
(Anurag Dwivedi)
General Manager (Procurement)
For & on behalf of BPPI
Ph: 011-49431811