

## AMENDMENT NO. 4

No. BPPI/SURGICAL/RC-097/2019

Dated: 10.04.2019

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

**Reference: - Tender Document & Amendment No.2**

The following amendment in Tender Document is hereby authorised:

S.no.	Tender Clause/ Reference No.	Item Code & Item Specification, unit size, packing.	Query	Amendment
1.	Annexure VIII, IX, BOQ, Clause 8.1 (vii) & Amendment No.2	<b>Item Code 5077: Rapid Diagnostic Malaria Test Kit</b> 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.	Clarification about the specification	The specification is hereby amended as: - <b>Rapid Diagnostic Malaria Test Kit</b> 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)/CE/USFDA The invalid rate should be less than 5% Should have space for recording particulars of test.
2.	Annexure VIII, IX, BOQ, Clause 8.1 (vii) & Amendment No.2	<b>Item Code 5078: Dengue NS1 Ag + Ab Combo Kit</b> (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%	Clarification about the specification	The specification is hereby amended as: - <b>Dengue NS1 Ag + Ab Combo Kit</b> (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%

		<p>Specificity: IgM - 97-100%, IgG - 97-100, Ag – 98-100%</p> <p>Shelf life 24 months</p> <p>Storage 2- 30°C.</p>		<p>Specificity: IgM - 97-100%, IgG - 97-100, Ag – 98-100%</p> <p>Shelf life 24 months</p> <p>Storage 2- 30°C.</p> <p>ISO 13485 (QMS)/CE</p>
3.	Annexure VIII, IX, BOQ, Clause 8.1 (vii) & Amendment No.2	<p><b>Item Code 8122: GLUCOMETER DIGITAL (1 glucometer- 25 strips, 25 lancets,1 lancing device,1battery 3v. Warranty card)</b></p> <p><b><u>Glucometer Specification:</u></b></p> <p>Glucose ranges : 30 - 800 md/dL</p> <p>Analysis time : 5 Sec</p> <p>Sample Volume : &lt; 1.0 micro-litres</p> <p>Sample : Whole Blood</p> <p>Fill detection : Automatic</p> <p>Battery : 3v Lithium Battery</p> <p>(Replaceable) (CR2032), should work for minimum 1000 test</p> <p>Minimum memory : 50 samples (Erasable)</p> <p>Replacement Warranty Period : 3 Years</p> <p>Storage Temp. : 0-50°C</p> <p>Operating Temp. : 2-50°C</p> <p>Relative Humidity : 10-95% (Non Condensing)</p> <p>Code : No Coding</p> <p>Strip Ejector facility to avoid contamination with blood.</p> <p>ISO 13485 (QMS)</p> <p><b>Note:</b> Control Solution for calibration of device</p> <p><b>Customer Care Toll Free Number:</b> Customer Care Toll Free Number must be provided by the Awardee bidder for the customer support.</p>	Clarification about the specification	<p>The specification is hereby amended as: -</p> <p><b>GLUCOMETER DIGITAL (1 glucometer- 25 strips, 25 lancets,1 lancing device,1battery 3v. Warranty card)</b></p> <p><b><u>Glucometer Specification:</u></b></p> <p>Glucose ranges : 30 - 800 md/dL</p> <p>Analysis time : 5 Sec</p> <p>Sample Volume : &lt; 1.0 micro-litres</p> <p>Sample : Whole Blood</p> <p>Sample Mode : Capillary</p> <p>Fill detection : Automatic</p> <p>Battery : 3v Lithium Battery</p> <p>(Replaceable) (CR2032), should work for minimum 1000 test</p> <p>Minimum memory : 50 samples (Erasable)</p> <p>Replacement Warranty Period : 3 Years</p> <p>Storage Temp. : 0-50°C</p> <p>Operating Temp : 2-50°C</p> <p>Relative Humidity : 10-95% (Non Condensing)</p> <p>Code :Auto Coding/No Coding</p> <p>Display: 48mm (diagonally) LCD (±5mm)</p> <p>Strip Ejector facility to avoid contamination with blood.</p> <p>ISO-15195:2013 (International Standard)</p> <p>CE Certificate</p>

				NIB (National Institute of Biological) Tested <b>Note:</b> Control Solution for calibration of device <b>Customer Care Toll Free Number:</b> Customer Care Toll Free Number must be provided by the Awardee bidder for the customer support.
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**Note: (i) All other contents of tender document remain unaltered.**

**(ii) Please quote your prices considering all Amendments, Annexures & BOQ.**

Sd/-

(Anurag Dwivedi)

General Manager (Procurement)

For & on behalf of BPPI

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