

**Amendment No. 02****Sub: Amendment to the referred tender enquiry****Ref.: Tender Enquiry No. HITES/PCD/PMSSY-IV/16/GNS/2021-22 dated 20-07-2021 and its Amendment No 01 dated 16-Aug-2021.**

Following changes are being incorporated in the above referred Tender Enquiry Document.

**SECTION VII**  
**Technical Specification**

<b>Tender Page &amp; Para</b>	<b>TENDER SPECIFICATION</b>	<b>READ AS</b>
<b>Item No. 1 Multipurpose OT Table</b>		
Pg 42 Para 3.h	Table should have mobile base with lockable castors	Table should have mobile base with lockable castors. <b>It should have self-levelling floor locks.</b>
Pg 42 Para 3.i	Should have built in electronic controlled kidney position with additional manual / electronic control by Kidney Bridge for better positioning if required	Should have built in electronic controlled kidney position with additional manual / electronic control by Kidney <b>Bridge/Break</b> for better positioning if required
Pg 42 Para 3.g	Mattress should be radiolucent and of PU make and suitable for fluoroscopy	Mattress should be radiolucent and of PU make and suitable for fluoroscopy. <b>Preferably Mattress for each section of the table should be separate</b>
Pg 42 Para 4.h	Width: 550 mm or less	Width: 550 mm or more
Pg 42 Para 4.j	Cranial and caudal traversing or longitudinal movement of minimum 200 mm	Cranial and caudal traversing or longitudinal movement of minimum <b>200 mm either side</b>
Pg 43 Para 5.j	Power lift stirrup set with side rail clamp – 1 set	Power lift stirrup set with side rail clamp – 1 set Powered lift stirrup set should be remote operated & manually operated
Pg 43 Para 8.a	Should be US-FDA or European CE with 4 digit notified body number or Declaration of conformity for quoted model along with ISO 13485 or BIS certified for the quoted model	Should be BIS certified for the quoted model <b>OR</b> should meet IEC 60601-1, IEC 60601-1-2 & IEC 60601-2-46 standards and should submit valid test report for the quoted model from NABL accredited laboratory/ from the labs in their country of origin in case of foreign manufacturer
Pg 43 Para 8.b	Manufacturer should be ISO certified for quality standards	Manufacturer should be ISO 13485 certified for quality standards
Pg 43 Para 8.c	Electrical safety conforms to standards for electrical safety IEC 60601-1 General Requirements (or equivalent BIS Standard)	Deleted
Pg 44 Para 8.d	Shall meet internationally recognised standard for Electro Magnetic Compatibility (EMC) for electromedical equipment: IEC-60601-1-2: latest edition Or Equivalent BIS or should comply	Deleted

Tender Page & Para	TENDER SPECIFICATION	READ AS
	with 89/366/EEC; EMC-directive as amended	
Pg 44 Para 8.e	Certified to be compliant with IEC 60601-2-46: Particular requirements for the safety of Operating Tables: latest edition or equivalent	Deleted
Pg 44 Para 8.f	The IEC certificate namely IEC 60601-1, IEC-60601-1-2, IEC 60601-2-46 along with full test report as per IEC guideline for the quoted model should be submitted from anyone of the labs mentioned below TUV, SGS, Intertek, UL, SAMEER, Bharat Test House, Astute Labs or from the labs in their country of origin	Deleted
<b>Item No. 2 Minor OT Table (Hydraulic)</b>		
3.2	Measurements:(approximate)	Measurements: ( <b>±5% tolerance allowed in the sizes/measurements/ angles/dimensions</b> )
Pg 45 Para 3.2.a	Height: 750-1040 mm (with 50 - 70mm mattress)	Height: 690-1080mm(with 50 -70mm mattress)
Pg 45 Para 3.2.b	Side tilt: + 15-20 degrees	Side tilt: Minimum + <b>/-15 deg</b>
Pg 45 Para 3.2.h	Width: 550 mm	Width: <b>550 mm or more</b>
Pg 46 Para 6.1	Should be BIS/US FDA or European CE approved product	Deleted
Pg 46 Para 6.2	Manufacturer and supplier should be ISO certified for quality standards	Manufacturer should be <b>ISO 13485</b> certified for quality standards
<b>Item No. 3 OT light for Minor OT</b>		
Pg 47 Para 2.b	Colour Temperature range: 3800k-5000 (±10 %) - Variable colour temperature	Colour Temperature range: 3800k-5000 (±10 %) - Variable colour temperature, should be adjustable from control panel
Pg 47 Para 2.f	Controls : Control Panel (wall and on dome)	Controls : Control Panel (wall or wireless remote and on dome)
Pg 47 Para 2.o	Surgical Light System should be compliant with relevant European CE/ US FDA/BIS standards.	Should be BIS certified for the quoted model OR should meet IEC 60601-1, IEC 60601-1-2 & IEC 60601-2-41 standards and should submit valid test report for the quoted model from NABL accredited laboratory/ from labs in their country of origin in case of foreign manufacturer
		<b>Added para:</b> Colour Rendering Index of light should be 90 or more

Tender Page & Para	TENDER SPECIFICATION	READ AS
		<b>Added Para:</b> Life of the LED should be 50,000 hrs. or more
<b>Item No. 4 Mobile Examination Light</b>		
Pg 47 Para 1.5	5 spokes stand mounted on caster of 5cm diameter.	5 spokes stand mounted on lockable casters of approx. 5cm diameter.
Pg 47 Para 1.6	Maximum height – 170 cms	Height: <b>Minimum 150 cms.</b>
Pg 47 Para 1.8	Cable length – 2m	Cable length : <b>2 -5m</b>
Pg 47 Para 2.1	Manufacturer should have ISO certification	Manufacturer should be ISO 13485 certified for quality standards
		<b>Added Para:</b> Colour Rendering Index of light should be 90 or more
<b>Item No. 5 Electro Cautery System</b>		
Pg 48 Para 13	The maximum power of different type outputs should be as:- Monopolar Cutting Max - 300W- 400W Bipolar Cutting 90 W or more Bipolar Coagulation 90 W or more Spray Coagulation – Max 120 W at 300 Ohms	The maximum power of different type outputs should be as:- Monopolar Cutting Max - 300W- 400W Bipolar Cutting 90 W or more Bipolar Coagulation 90 W or more Spray Coagulation – <b>90 W or more</b>
Pg 48 Para 14	All the Accessories should be mentioned in BOQ and rate of each accessories should be quoted separately which should be valid for the entire warranty period. The unit should be supplied with all standard accessories such as – Reusable push button Handpiece – 2 nos. / Disposable - 200 nos., Electrode set of 10 Nos. each (Pin point, flat tip-short, flat tip- long blade), Explosion protective double pedal foot switch – 1 no, Reusable Siliconearth pad – 2/Disposable - 200 nos., bipolar forcep with cord straight & angled (18-19.5cm & 19-22.5cm) -2 nos. each. All accessories should be of same make of Main Equipment	All the Accessories should be mentioned in BOQ and rate of each accessories should be quoted separately which should be valid for the entire warranty period. The unit should be supplied with all standard accessories such as – <b>Push button Handpiece – Disposable - 200 nos.,</b> Electrode set of 10 Nos. each (Pin point, flat tip-short, flat tip- long blade), Explosion protective double pedal foot switch – 1 no, <b>Siliconearth pad – 4 nos reusable (2 adult &amp; 2 Paediatric) &amp; Adult Disposable - 200 nos.,</b> Bipolar forcep with cord straight & angled bayonet (18-19.5cm & 19-22.5cm) -2 nos. each. All accessories should be of same make of Main Equipment
Pg 48 Para 15	The equipment should be European CE with 4 digit notified body no or US FDA or BIS safety standard. It should have IEC 60601-1 certificate	Equipment should be BIS or European CE with four digit notified body number or US FDA approved for the quoted model and certificate to be submitted. <b>OR</b> should meet IEC 60601-1, IEC 60601-1-2 & IEC 60601-2-

Tender Page & Para	TENDER SPECIFICATION	READ AS
		2 standards and should submit valid test report for the quoted model from NABL accredited laboratory/ from labs in their country of origin in case of foreign manufacturer
		<b>Added Para:</b> Should be upgradable to Argon Plasma System and Smoke Evacuation system technology
		<b>Added para:</b> It should have touch screen display of minimum 5 inches or more
		<b>Added para:</b> Should be programable in nature, minimum 30 editable user programs can be made
BOQ.2	Reusable push button Handpiece 2 Nos. OR Disposable push button Handpiece 200 Nos	Disposable push button Handpiece 200 Nos.
BOQ.3	Electrode set (Pin point, flat tip-short, flat tip- long blade) - 10 Nos each	Electrode set (Pin point) - 10 Nos. Electrode set (flat tip-short) - 10 Nos. Electrode set (flat tip- long blade) - 10 Nos.
BOQ.5	Reusable Siliconearth pad 2 Nos OR Disposable Siliconearth pad 200 Nos	Reusable Siliconearth pad - Adult - 2 Nos. Reusable Siliconearth pad - Paediatric - 2 Nos. Disposable Siliconearth pad - Adult - 200 Nos.
BOQ.6	Bipolar forcep with cord straight & angled (18-19.5cm & 19-22.5cm) - 2 Nos each	Bipolar forcep with cord straight (18-19.5cm) - 2 Nos. Bipolar forcep with cord angled bayonet (18-19.5cm) - 2 Nos. Bipolar forcep with cord straight (19-22.5cm) - 2 Nos. Bipolar forcep with cord angled bayonet (19-22.5cm) - 2 Nos.
<b>Item No. 6 Electro Surgical Unit with vessel sealing</b>		
Pg 50 Para 4.2.j	Resuable dedicated instruments for open and laparoscopic for vessel sealing use (Life of minimum 50 caes), qty 02 of each/Disposable - 20 nos. each	Reusable dedicated instruments for open and laparoscopic <b>for integrated cutting &amp; vessel sealing use</b> (Life of minimum 50 case), <b>qty 02 nos. of each and Disposable - 20 nos. each</b>
Pg 50 Para 7.1	Should be USFDA or European CE with 4 digit notified body number/BIS approved product	Equipment should be European CE with four digit notified body number or US FDA or BIS approved for the quoted model and certificate to be submitted. <b>OR</b> should meet IEC 60601-1, IEC 60601-1-2 & IEC 60601-2-2 standards and should submit valid test report for the quoted model from NABL accredited laboratory/ from labs in their country of origin in case of foreign manufacturer
Pg 50 Para 7.2	Manufacturer should have EN ISO certification for quality standards.	Manufacturer should have valid ISO 13485 certification for quality standards.
BOQ.9	Bipolar forceps (non stick) with cable, straight (small and large), and	Bipolar forceps (non stick) with cable, straight (small) - 2 Nos.

Tender Page & Para	TENDER SPECIFICATION	READ AS
	Bayonet (small and large) 2 Nos. each	Bipolar forceps (non stick) with cable, straight (large) - 2 Nos. Bipolar forceps (non stick) with cable Bayonet (small) - 2 Nos. Bipolar forceps (non stick) with cable, Bayonet (large) - 2 Nos.
BOQ 11	Reusable dedicated instruments for open and laparoscopic for vessel sealing use (Life of minimum 50 caes) - 2 nos each OR Disposable 20 Nos. each	Reusable dedicated instruments for open surgery for integrated cutting & vessel sealing use (Life of minimum 50 case) - 2 Nos. Reusable dedicated instruments for laparoscopic surgery for integrated cutting & vessel sealing use (Life of minimum 50 case) - 2 Nos. Disposable dedicated instruments for open surgery for integrated cutting & vessel sealing use - 20 Nos. Disposable dedicated instruments for laparoscopic surgery for integrated cutting & vessel sealing use - 20 Nos.
		<b>Added Para:</b> Should be upgradable to Argon Plasma System and Smoke Evacuation system technology
<b>Item No. 8 Open Surgery Instruments (Set) for General Surgery</b>		
Pg 54 Para 2.1	The instruments quoted should be of high quality and standard	All the instruments should be made of corrosion free surgical grade stainless steel SS 400 grade and bidder should submit original OEM certificate for the same
Pg 54 Para 2.2	Instrument should be BIS or European CE or USFDA approved & copy to be enclosed	Deleted
Pg 54 Para 2.3	The instruments must be ISO certified and copy to be enclosed	Manufacturer should have valid ISO 13485 certification for quality standards.
Pg 54 Para 2.6	The 90 % of the total items should be quoted from the same manufacturer and 10 % can be from 3rd party.	The 80 % of the total items should be quoted from the same manufacturer and 20 % can be from different manufacturer
Pg 54 Para 1.d	Sponge Holding Forceps FOERSTER-BALLENGER. Serrated jaws; curved 245 mm long	Sponge Holding Forceps FOERSTER-BALLENGER. Serrated jaws; curved 245 mm long - 6 Nos.
Pg 54 Para 16.a	Pott"s Smith Scissors 180-190 mm long; 25 degree with bead at the tip of posterior blade	Deleted
Pg 60 Para 107	Container Systems: Metal For sterilization and hand instruments and other accessories. Different sizes - 3	Container Systems: Metal For sterilization and hand instruments and other accessories: 1 no each 500-600 x 200-250 x 100 mm 500-600 x 200-250 x 135 mm 500-600 x 200-250 x 150 mm
<b>Item No. 9 ETO sterilizer</b>		
Pg 61 Para 10	Gas cartridges should be EPA certified.	Deleted

Tender Page & Para	TENDER SPECIFICATION	READ AS
Pg 62 Para 12	The ETO sterilizer should have compliance to BS EN ISO 9001. Certificate to be provided by equipment manufacturer	Deleted
<b>Item No. 10 Laparoscope Set</b>		
Pg 64 Para 3.1.g	Facility of direct recording into external storage from camera HUB should be available (Optional)	Facility of direct recording into external storage from camera HUB should be available
Pg 65 Para 3.5	LIGHT SOURCE (Xenon 300W) with One Spare Bulb or Comparable LED Light source.	LED LIGHT SOURCE
Pg 65 Para 3.5.1	Xenon cold light fountain with 300 watts xenon lamp/LED light source equivalent to 300 W Xenon lamp	LED light source equivalent to 300 W Xenon lamp or 300 W LED Light source
Pg 65 Para 3.5.4	Display of lamp life/Bulb usage meter warning light in case of Xenon lamp or minimum 5000 hours lamp life in case of LED	Minimum 20000 hours lamp life
<b>3.6</b>	<b>SUCTION-IRRIGATION UNIT</b>	
Pg 66 Para 3.6.7	Accessories should include silicone suction tubing set, reusable pressure domes, bacterial filter and sterilizable suction bottles with cap of 3-5 lit capacity (2nos)	Accessories should include silicone suction tubing set, reusable pressure domes, bacterial filter and sterilizable suction bottles with cap of <b>2 litre or more</b> capacity (2nos)
<b>3.7</b>	<b>VIDEO-CART (Same Make)</b>	<b>VIDEO-CART</b>
Pg 66 Para 3.8.c	Writes multi-session and multi-patient CDs/DVDs	Writes multi-session and multi-patient in to CDs/DVDs/USB
Pg 66 Para 3.8.l	Flat screen colour monitor of 1024x768 resolution with all connectors and connection cables (BNC, S-VIDEO(Y/C), VGA), which should be specified	Flat screen colour monitor of <b>minimum 1024x768</b> resolution with all connectors and connection cables (BNC, S-VIDEO(Y/C), VGA), which should be specified
Pg 67 Para 3.8.n	It should have operating system of Windows Xp or latest.	It should have latest windows operating system & colour laser printer
Pg 67 Para 3.10	HAND INSTRUMENTS & OTHER ACCESSORIES	
Pg 67	Reusable Veress Pneumoperitoneum Needle: Spring loaded blunt stylet luer lock length - (10 -12cm) and 15 cm - 2 each	Reusable Veress Pneumoperitoneum Needle: Spring loaded blunt stylet luer lock length - <b>(10 -13cm)</b> and 15 cm - 2 each
Pg 68	Hook Scissors; Double action jaws , rotating with connector pin for unipolar coagulation,	Hook Scissors; <b>Single</b> action jaws , rotating with connector pin for unipolar coagulation, size 5mm, length 33-36cm, dismantling facility, ,

---

<b>Tender Page &amp; Para</b>	<b>TENDER SPECIFICATION</b>	<b>READ AS</b>
	size 5mm, length 33-36cm, dismantling facility,, autoclavable - 1 No	autoclavable - 1 No
Pg 69	Fibreoptic Light cables With straight connectors of 4.8mm diameter and 250 cm long - 1	Fibreoptic Light cables With straight connectors of 4.8mm diameter and <b>230-250 cm</b> long - 1

**Note:**

- i. Prospective Bidders are also advised to check the website regularly prior to the closing date and time of online submission of bids.
- ii. All other contents of the tender enquiry including terms & conditions remain unaltered.
- iii. TC compliance sheet v1.0 and Price bid format v1.0 is being uploaded on CPP Portal for necessary actions of interested Bidders.