11-03-2020

Amendment No. 2

Sub: Amendment to the referred tender enquiry

Ref.: HITES/PCD/AIIMS-IV/25/OBG/19-20 dated 29-01-2020 read with amendment no. 1 dated 09.03.2020

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

Item No. 1 Laparoscopic Surgery Set with Hysterestoscope & resectoscope with High Definition Camera & Monitor (2020_HLL_41504_1)		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS
Pg 45 Para 2. 1.	Telescopes, Insufflator, Suction irrigation Unit, Camera Control Unit and Camera head, HD Medical grade monitor, Light source, Image management system, Hysteroscope & Resectoscope should be from same manufacturer with USFDA or European CE approved	Telescopes, Insufflator, Camera Control Unit and Camera head, HD Medical grade monitor, Light source, Image management system, should be from same manufacturer with USFDA or European CE approved Hysteroscope & Resectoscope should be from same principal manufacturer; incase these items are not manufactured by the principal manufacturer, the same shall be offered from a second manufacturer (In this case the principal manufacturer should submit an undertaking for non production of these items with USFDA or European CE approved).
Pg 45 Para 2. 2.	Morcellator with accessories, CO2 cylinder (Type – B, 5 Kg), Video Color printer/Laser color printer and Electro cautery should be compatible with the principal system and it should be USFDA or European CE approved.(Except CO2 cylinder).	Suction irrigation Unit, Morcellator with accessories, CO2 cylinder (Type – B, 5 Kg), Video Color printer/Laser color printer and Electro cautery should be compatible with the principal system and it should be USFDA or European CE approved.(Except CO2 cylinder).
Pg 45 Para 2. 3.	Regarding hand instruments : 80% of the hand instruments should be supplied from same principal manufacturer and all the instruments should be USFDA or European CE approved	Regarding hand instruments : 70% - 80% of the hand instruments should be supplied from same principal manufacturer and all the instruments should be USFDA or European CE approved/ BIS Certified
Pg 45 Para 3.1	Colour coded for identification	Colour coded for identification (Optional)
	Added Para	Tray for storing of Telescopes - Autoclavable

Pg 45 Para 3.2 1.	Reusable Veress Pneumoperitoneum Needle- Spring loaded blunt stylet luer lock length8- 10/15cm/12cm - 4 each	Reusable Veress Pneumoperitoneum Needle- Spring loaded blunt stylet luer lock, working length 10cm/15cm/12cm - 4 each
Pg 45 Para 5.	Grasping forceps curved - toothed 2x4 teeth-2 each- Double action jaws, rotating with connector pin for unipolar coagulation, size 5mm, length 33-36 cm, dismantling facility, size 10mm - 2 each (5 & 10 mm)	Grasping forceps curved - toothed 2x2 to 2x3 teeth-2 each-Double action jaws, rotating with connector pin for unipolar coagulation, size 5mm, length 33-36 cm, dismantling facility, size 10mm - 2 each (5 & 10 mm)
Pg 46 Para 29	Fascia closure instrument-Size 2.8mm, length 17cm - 2nos	Fascia closure instrument-Size 2.5 to 2.9mm, length 15-18cm - 2nos
Pg 47 Para 41. b.	Morcellator tube serrated edge	Morcellator tube serrated / plain edge
Pg 47 Para 41. c.	Atraumatic trocar sleeve with pyramidal trocar 12 mm.	Atraumatic trocar sleeve with pyramidal trocar 12-15 mm.
Pg 47 Para 41. e.	Insulated sheath.	Deleted
Pg 47 Para 41. f.	Laparoscopic Bag	Laparoscopic Bag - 50
Pg 47 Para 41. g.	Insulated handle with HF connection rotating with ratchet.	Deleted
Pg 47 Para 3.3 b)	Flow rate of 20-30 litres per minute	Flow rate of 45-50 litres per minute
Pg 47 Para 3.3 g)	Facility for filtering preheating of gas to body temperature.	Facility for filtering preheating of gas to body temperature - integrated / external heating
Pg 47 Para 3.3 h)	Facility for easy evacuation of smoke and mist.	Facility for easy evacuation of smoke and mist smoke evacuation system integrated / external (Synergistic with ESU optional)
Pg 48 Para 3.5 b)	Irrigation pressure 550mm Hg or more	Irrigation pressure 400 mm or more
Pg 48 Para 3.5 c)	Suction pressure 0.65 bar or more	Suction pressure 0.5 bar or more
Pg 48 Para 3.5 g)	Irrigation suction flow rate should not be less than 2- 5 L/min.	Irrigation suction flow rate should not be less than 1.5 - 5 L/min.

Pg 48 Para 3.7	Formaline chamber made of Virgin Acrylic 4.5mm thickness; size : 26"X8"X8" (LXBXH) with three tray, for sterilizing the laparoscope & Hysteroscope - 04 nos	Deleted
Pg 48 Para 3.9 c)	Camera control unit with three chip HD camera head having HD CCD chip of same aspect ratio of 16:9 and camera control unit should be able to produce following video output : DVI-D-2 Nos, SDI - 1 no, Composite Video - 1 no.	Camera control unit with three chip HD camera head having HD CCD / CMOS chip of same aspect ratio of 16:9 and camera control unit should be able to produce following video output : DVI- D/HDMI/SDI - 3 no
Pg 48 Para 3.9 d)	Three chip camera head should produce at head itself Pure Digital Signal with High Definition video (1920 * 1080PI) with aspect ratio of CCD chip and video format of 16:9 or 16:10.	Three chip camera head should produce at head itself Pure Digital Signal with High Definition video (1920 * 1080PI) with aspect ratio of CCD / CMOS chip and video format of 16:9 or 16:10.
Pg 48 Para 3.9 e)	System should have integrated Optical Zoom (12- 28mm, 2 X) to enhance image size and focus lens/rings to make it fully soakable and waterproof	System should have Optical Zoom (16-28mm , 2 X) to enhance image size and focus lens/rings to make it fully soakable and waterproof
Pg 48 Para 3.9 g)	Three Chip Camera control unit should be compatible with all the tree chip camera head and the company should provide standby facility within 48 hours of breakdown.	Three Chip Camera control unit should be compatible with three chip camera head and the company should provide standby facility within 48 hours of breakdown.
Pg 48 Para 3.9 h)	Should be compatible for remote controlled operation of various features	Should be compatible for remote controlled operation of various features through camera head
Pg 48 Para L)	Image sensor CCD Chip	Image sensor CCD / CMOS Chip
Pg 48 Last second Para	Video Outputs Composite to BNC, Y/C to S-VHS, RGB to D Socket HDTV-DVI-D, DV for recording	Video Outputs DVI-D/HDMI/SDI
	Added Para	Camera head should be sterilizable or autoclavable
Pg 49 Para 3.10 b)	LCD/LED Crystal display	LCD/ Backlit LED display
Pg 49 Para 3.10 c)	26" High Resolution HD video Medical grade monitor - 1 no	26" or more High Resolution HD video Medical grade monitor - 1 no
Pg 49 Para 3.10 e)	SDI/HD-SDI, Composite, S-Video RGB, DVI-D, VGA input, S-VHS - 2 nos, should also have same video output	DVI-D/HDMI/SDI input - 2 nos, should also have same video output
Pg 49 Para 3.11 a)	Xenon 300 Watts	LED Light Source equivalent to 300 Watts

Pg 49 Para 3.11 c)	Lamp life 500 hrs or more with at least one spare bulb.	Lamp life 10000 hrs or more	
Pg 49 Para 3.11 j)	Should be able to produce colour temperature of 6000K.	Should be able to produce colour temperature of 5800 - 6400K.	
Pg 49 Para 3.12	VIDEO -CART (Should be from the same manufacturer / or ANY International BRAND)	VIDEO-CART (Should be from the same OEM)	
Pg 49 Para 3.13 d)	Integrated DVD/CD/Blue Ray Disc Writer with maximum speed which should be specified.	Integrated DVD/CD /USB /Blue Ray Disc Writer with maximum speed which should be specified.	
Pg 49 Para 3.13 g)	All types of connecting cables (BNC, DVI) and connectors, which should be specified.	Deleted	
Pg 49 Para 3.13 h)	With all connectors and connection cables (BNC, S- VIDEO(Y/C), VGA), which should be specified	With all connectors and connection cables, which should be specified	
Pg 50 Para 3.13 k)	Full HD recording, Medical grade computer and Monitor, Touch screen, Minimum 500 GB storage memory. It should have window based operating system, minimum Windows - XP.	Full HD recording, Medical grade computer and Monitor, Touch screen, Minimum 1 TB storage memory. It should have window based operating system, minimum Windows - XP.	
Pg 50 Para 4.3 A) a)	Operating and Contact - Hysteroscope Forward- Oblique Telescope 30°, enlarged view magnification 1x, 60x, diameter 4.0 mm, length 30 cm, autoclavable, fiber optic light transmission incorporated, - 1 no.	Operating Hysteroscope length 30 cm, autoclavable, fiber optic light transmission incorporated, - 1 no. Contact - Hysteroscope Forward-Oblique Telescope 30°, enlarged view magnification, diameter 4.0 mm, length 30 cm, autoclavable, fiber optic light transmission incorporated, - 1 no.	
Pg 50 Para 4.3 B)	Diagnostic Sheath with Obturator 5 mm diameter for the above 4 mm Hysteroscope telescopes (Item A), with luer lock adapter.	Diagnostic Sheath with / without Obturator 5 mm diameter for the above 4 mm Hysteroscope telescopes (Item A), with luer lock adapter.	
Pg 52 Para 5. 2.	Arc controlled cutting with a pre selectable power of 200 watts in both unipolar and bipolar modes.	Arc controlled cutting with a pre selectable power of 200 - 300 watts in both unipolar and bipolar modes.	
Pg 53 Para 9.1	Should be USFDA or European CE approved product	Should be USFDA or European CE with 4 digit notified body no. or BIS Certified.	
	Item No. 2 Portable Ultrasound & Colour Doppler (2020_HLL_41504_2)		
Tender Page &	TENDER SPECIFICATION	AMENDED AS	

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Para		
Pg 54 Para 2	The unit should have a laptop type console design. The unit should be compact, lightweight and portable. Weight should not less than or equal to 11 Kg including battery (excluding cart and accessories).	The unit should have a laptop type console design. The unit should be compact, lightweight and portable. Weight should be less than or equal to 8 Kgs including battery (excluding cart and accessories).
Pg 54 Para 12	The System must have integrated high – resolution TFT/LCD/Single monitor of 12" Inches & more.	The System must have integrated high – resolution TFT/LCD /LED /Single monitor of 12" Inches & more.
Pg 54 Para 14	The system should have the facility of digital storage and retrieval of B/W and colour image data on built- in CD/DVD Drive. Provision for USB port and LAN transfer of data should also be present.	The system should have the facility of digital storage and retrieval of B/W and colour image data on built-in CD/DVD Drive /USB. Provision for USB port and LAN transfer of data should also be present.
Pg 54 Para 15	Imaging modes of Real time 2D, Colour Doppler, Pulsed wave Doppler and Power (energy) Doppler, Tissue Harmonic Imaging with contrast to be quoted as standard feature.	Imaging modes of Real time 2D, Colour Doppler, Pulsed wave Doppler and Power (energy) Doppler, Tissue Harmonic Imaging, CW with complete cardiac package to be quoted as standard feature and upgradable to 4D.
Pg 55 Para 21	Facility for storage on CDR should be available.	Facility for storage on CDR /USB should be available.
Pg 55 Para 25	Paper and cartridges for 1000 image printouts should be provided with the unit.	Paper and cartridges (optional) for 1000 image printouts should be provided with the unit.
Pg 55 Para 26	The unit offered must be sturdy and should be able to withstand accidental hits and falls during transportation.	The unit offered must be sturdy during transportation.
Pg 54 Para 33	The unit should be United States Food and Drug Administration (FDA) or Conformité Européenne (CE) approved.	Should be USFDA or European CE with 4 digit notified body no. or BIS Certified.
	Item No. 3 Cardiotocography Machi	ne (2020_HLL_41504_3)
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS
Pg 56 Para 3.1 2)	Should have inbuilt LCD/TFT screen with tilt adjustment up to 90 degree with facilities to display on screen fetal heart tracings and toco tracings.	Should have inbuilt LCD/TFT screen with wide view angle adjustment up to 90 degree with facilities to display on screen size 8-10 " fetal heart tracings and toco tracings.

heart tracings and toco tracings.

Pg 56 Para 5	Highly Sensitive ultra sound transducer which should be 1.5MHZ for less signal attenuation and good signal acquisition. Ultrasound transducer should be a waterproof unit. Designed with Snap Clasp closure for easy application and cleaning. Should have facility to connect any transducer in any socket for easy use. Preferably there should be facility to switch between transducers when more than one transducer is used.	Highly Sensitive ultra sound transducer which should be 1.5MHZ for less signal attenuation and good signal acquisition. Ultrasound transducer should be a waterproof unit.
Pg 57 Para 7.1	The unit should be United States Food and Drug Administration (FDA) or Conformité Européenne (CE) approved.	Should be USFDA or European CE with 4 digit notified body no. or BIS Certified.
	Item No. 4 Gynae OT Table (20)20_HLL_41504_4)
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS
Pg 58 Para 21.	The robust handset should offer 8 controls namely Trend/ Reverse Trend, Lateral Tilt, Flexion/ Extension and Height functions.	The robust handset should offer minimum 8 controls namely Trend/ Reverse Trend, Lateral Tilt, Zero position, Longitudinal slide and Height functions.
Pg 58 Para 22.	Brakes, 4 nos. Wheels	Brakes, 4 nos. Wheels. Self-levelling facility (Optional)
Pg 58 Para 25.	The Table should be operated by the following operating elements: corded hand control, Manual override panel with manual override facility.	The Table should be operated by the following operating elements: corded hand control, Manual override panel with manual override facility / electrical override facility.
Pg 58 Para C.	Length: 6-6.5 ft	Length: 1900 mm or more
Pg 58 Para C.	Break (extension) position: 200-220 deg	Deleted
Pg 58 Para C.	Break (flexion) position : 100-130 deg	Deleted
Pg 59 Line no. 15	Arm support, perplex- 2 pcs	Deleted
Pg 59 Para D	Environmental factors: Shall meet IEC-60601-1-2 :2001 (Or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility or should comply with 89/366/EEC; EMC-directive.	Environmental factors: Shall meet IEC-60601-1-2 :2001 and IEC-60601-2- 2
Pg 59 Para F	Should be USFDA or European CE approved product	Should be USFDA or European CE or ISO 13485 along with EC Declaration of Conformity or BIS
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		approved product	
	Item No. 5 Delivery Bed (2020_HLL_41504_5)		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS	
Pg 60 Para 3.1 1.	It should have control devise from making height (44cm to 90cm) and back adjustment (Manual as well as remote control)	It should have control devise from making height (50cm to 90cm) and back adjustment (Manual as well as remote control)	
Pg 60 Para 3.1 5.	Should have wheels (dia-6" or 8") provided with locking system.	Should have wheels provided with center locking system (twin wheel castors)	
Pg 61 Para 7.1	Should be European CE or US FDA	Should be European CE or US FDA or BIS Certified.	
	Item No. 6 LEEP SYSTEM with Smoke Evacuator & integrated cart (2020_HLL_41504_6)		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS	
Pg 62 Para	electrode 2cmx0.8cm, 12c	electrode 0.5 cm to 1 cm (04 nos), 1 cm to 2 cm (02 nos)	

13. 11)		
Pg 62 Para 14	Should be USFDA or European CE approved	Should be USFDA or European CE with 4 digit notified body no. or BIS Certified.

Tender Page & Para	TENDER SPECIFICATION	AMENDED AS
Pg 63 Para 3.	Gas consumption for freezing: ca.35g – 50 g/min.	Deleted
Pg 63 Para 4.	Max. exhaust gas volume: 40-60 l/min	Deleted
Pg 63 Para 6.	A different indicator lamp to indicate freezing and defrosting phase.	A different indicator (dual trigger system for freezing and deep freezing) lamp to indicate freezing and defrosting phase.
Pg 63 Para	It should be supplied with multiple different sized probe-tips to cater for cervical cryocautery of lesion	It should be supplied with multiple different sized probe-tips to cater for cervical cryocautery of
11.	of all sizes.	lesion of minimum 4 sizes.

Pg 63 Para 13.	Should be European CE or US FDA approved.	Should be USFDA or European CE with 4 digit notified body no. or BIS Certified.	
	Item No. 8 Caesarean set (2020_HLL_41504_8)		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS	
Pg 64 Para 20	Green Armytage X"s series	Green Armytage 8"	
Pg 64 Last Para	All instruments should be US FDA or European CE approved	Deleted	
NA	NA	Added Para: The size variation of +/- 10% is acceptable	
NA	NA	Added Para: All Surgical instruments should be made of 4 series AISI 420 and AISI 410 steel and certified copy must have to submit at the time of tender submission. Manufacturer should be ISO 13485 certified. The brand name along with catalogue number should be engraved on each instruments All instruments should be from same principal manufacturer; incase any of the instrument is not manufactured by the principal manufacturer the same shall be offered from a second manufacturer; not exceeding 20% of total quantity of instruments. (In this case the principal manufacturer should submit an undertaking for non production of such instruments).	
	Item No. 9 Hysterectomy set (2	020_HLL_41504_9)	
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS	
Pg 65 Para 25	Balfour Retractor 10" shaft for abdominal hysterectomy Doyen"s 8" shaft	Doyen's abdominal retractor 8" shaft	
Pg 65 Para 28	Heaney Atrauma Straight UNS-370-23 Hysterectomy Clamps	Heaney Atrauma Straight Hysterectomy Clamps	

Pg 65 Para 29	Heaney Atrauma Straight UNS-371-22 Hysterectomy Clamps	Heaney Atrauma Straight Hysterectomy Clamps	
Pg 65 Para 31	Mayo"s Scissors (TC TIP)	Mayo"s Scissors (TC TIP) - 6" and 8"	
Pg 65 Para 32	Kelly Clamps	Kelly Clamps - 8''	
Pg 65 Para 33	Right Angled Clamps	Right Angled Clamps - 8"	
Pg 65 Para 35	Micro needle holder (TC TIP)	Micro needle holder (TC TIP) - 4"-6"	
Pg 65 Para 36	Microscissors (TC TIP)	Microscissors (TC TIP) - 4"-6"	
Pg 65 Para 37	Wertheim"s Vaginal clamp	Wertheim"s Vaginal clamp - 8"	
Pg 65 Para 38	TC-parametrium scissors	TC-parametrium scissors - 8"	
Pg 65 Last Para	All instruments should be USFDA or European CE approved	Deleted	
NA	NA	Added Para: The size variation of +/- 10% is acceptable	
NA	NA	Added Para: All Surgical instruments should be made of 4 series AISI 420 and AISI 410 steel and certified copy must have to submit at the time of tender submission. Manufacturer should be ISO 13485 certified. The brand name along with catalogue number should be engraved on each instruments All instruments should be from same principal manufacturer; incase any of the instrument is not manufactured by the principal manufacturer the same shall be offered from a second manufacturer; not exceeding 20% of total quantity of instruments. (In this case the principal manufacturer should submit an undertaking for non production of such instruments).	
HITES/P	HITES/PCD/AIIMS-IV/25/OBG/(Amd-02)19-20 dated 11-03-2020 Page 9 of 11		

Item No. 10 MTP Suction (2020_HLL_41504_10)			
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS	
Pg 66 Para 3	Should be very quiet in operation.	Noise level should be less than 45 dB.	
Pg 66 Para 4	3 ltrs double suction container, polysulfone, graduated with lid for overflow protection and 2 spare suction tuby	3-5 ltrs double suction container, polysulfone, graduated with lid for overflow protection and 2 spare suction tube	
Pg 66 Para 9	It should be USFDA or European CE approved	Manufacturer should be ISO 13485 certified.	
Item No. 11 Multiparameter Monitor (2020_HLL_41504_11)			
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS	
Pg 67 Para 7.1	It should have US FDA or European CE with four digit notified body number certificate	Should be USFDA or European CE with 4 digit notified body no. or BIS Certified.	
Item No. 12 Syringe Infusion pump (2020_HLL_41504_12)			
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS	
Pg 68 Para 3	Should have US FDA or European CE with four digit notified body number cetificate	Should be USFDA or European CE with 4 digit notified body no. or BIS Certified.	
Item No. 13 ESU with Vessel Sealing (2020_HLL_41504_13)			
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS	
Pg 70 Para 4.2 (d)	Reusable Silicon neutral electrode for adults and children along, with cable and fixation device qty 01 each/Disposable - 100 nos each	Reusable Silicon neutral electrode for adults and children along, with cable and fixation device qty 01 each/Disposable - 50 nos each	
Pg 70 Para 4.2 (e)	Sterilizable reusable electrode handle with finger switch with cable for electrode handle, qty 02 nos/Disposable - 200 nos.	Sterilizable reusable electrode handle with finger switch with cable for electrode handle, qty 01 nos/Disposable - 50 nos	
Pg 70 para 4.2 (f)	set of electrodes (4 different types) with electrode container with holder, qty 5 of each type	set of reusable autoclavable electrodes (4 different types) with electrode container with holder, qty 5 of each type	

Pg 70 para 4.2 (h)	bipolar forceps (non stick) with cable, straight (small and large), and Bayonet (small and large), qty 02 of each type	bipolar forceps reusable autoclavable (non stick) with cable, straight (small and large), and Bayonet (small and large), qty 02 of each type
Pg 70 Para 7.1	Should be USFDA or European CE with 4 digit notified body number approved product	Should be USFDA or European CE with 4 digit notified body number /BIS approved product
Pg 71 BOQ Para 5	Reusable Silicon neutral electrode for adults and children along, with cable and fixation device qty 01 Nos each OR Disposable 100 Nos each	Reusable Silicon neutral electrode for adults and children along, with cable and fixation device qty 01 each OR Disposable - 50 nos each
Pg 71 BOQ Para 6	Sterilizable reusable electrode handle with finger switch with cable for electrode handle - 02 nos/Disposable - 200 nos OR Disposable 200 Nos	Sterilizable reusable electrode handle with finger switch with cable for electrode handle, qty 01 nos OR Disposable - 50 nos

All other contents of the Tender enquiry including terms & conditions remain unaltered. Note:

I. Prospective Bidders are also advised to check the website regularly prior to the closing date and time of online submission of bids