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Corrigendum-II

Bihar Medical Services and Infrastructure Corporation Limited (BMSICL) had invited E-Bids from the interested parties for the procurement, rate contract and the supply of medical equipment for different Govt. Institutions of Bihar vide Notice Inviting Re-tender No.- BMSICL/2023-24/ME-320. During and after Pre-bid meeting various suggestions were received from different prospective bidders regarding amendment in technical specification of equipment which were discussed and deliberated on by the experts, who after due deliberation recommended certain amendments in the technical specification of the equipment, which are annexed as Annexure-I of this corrigendum. Rest of the terms & conditions of the NIT & Corrigendum-I shall remain unchanged:-

Tender Reference No.	BMSICL/2023-24/ME-320
Last date and time of submission of online bids	26 th September 2023 till 17:00 Hrs.
Last date and time of submission of original documents of EMD, Tender Fee and Document	27 th September 2023 till 14:00 Hrs.
Date, Time and Place of opening of Technical Bid	27 th September 2023 (at 15:00 Hrs.) on the website of https:/eproc2.bihar.gov.in in the office of BMSICL
Date and time of opening of financial Bids	To be announced later on https:/eproc2.bihar.gov.in

Note:-

- 1. Bidders are advised to refer to the Annexure-I of this corrigendum before submission of bid.
- 2. Those who have submitted their bids are requested to re-submit their bids in accordance with this corrigendum.

Annexed:- as above

Sd/-GM (Procurement) BMSICL

	Annexure-I		
	Name of Equipment :- Laproscopy System with Hand Instruments		
SI. No	Technical Specification as per tender	Amendment	
	Suction Irrigation unit Compact		
	It shall be a combination of suction/irrigation pump for use in gynecological, laparoscopic and other endoscopic interventions. The adaptation to the correct mode of surgery intended should happen automatically and manually when the correct type of tubing is used. The insertion of pressure lines in to the unit should be simplified for ease of use. The unit should be equipped with electronic, safety circuits that cut the suction/irrigation operation if the unit departs consistently form the present values.	No Change	
	Laparoscopy Suction Irrigation pump can be any reputed make. It should be compatible with the system.	No Change	
	The suction/irrigation unit should have the following features:	No Change	
	It is compatible with the management system and can thus be controlled from inside/outside the sterile area via Touch screen/touch keypad	No Change	
	Easy to user controls for the control of functionalities.	No Change	
	Touch controls and digital displays ensure safe and precise adjustment of the set values.	No Change	
	During power – up, all system go through and automatic self- test and are only released after a positive result	No Change	
1	Safety functions that control any departure from operator settings.	No Change	
	Audible alarms in case of malfunction.	No Change	
	Should have a suction mode that automatically/manual maintains irrigation pressure and flow constant.	No Change	
	The suction/ lrrigation unit should have the following technical specifications:	No Change	
	Power Supply voltage: 100-240 VAC	No Change	
	Power frequency: 50-60 Hz	No Change	
	Power Supply voltage: 100-240 VAC	No Change	
	Power frequency: 50-60 Hz	No Change	
	Operating conditions: $+10^{0}$ c to $+40^{0}$ c	No Change	
	Irrigation:	No Change	
	Pressure Should between 10-400 or more mm Hg	No Change	
	Flow Rate should between 10ml-1000m/Min or More	No Change	
	Suction under-pressure:	No Change	
	Suction Pressure 0 to 0.6-0.8 Bar or 60-80 kpa	Suction Pressure 0 to 0.6-0.7 Bar or 60-75 kpa or more	

	Pressure Indicator digital display /LED light Marking display/ Bar Graph display	No Change
	flow Indicator digital display /LED light Marking display/Bar Graph display	No Change
	Certified to IEC 60601.1, CAN/CSA 22.2 No. 601.1-M90:	No Change
	Type of protection against electrical shocks shocks: protection class1	No Change
	Degree of protection against electrical shocks: Applied part of type BF	No Change
	Type of protection against moisture drip-water protection as per IPX 1 or equivalent	No Change
	Us FDA/ European CE (Issued by a notified body) approved Model should be offered.	No Change
	2. ELECTRONIC CO2 Insufflator. (1 No)	No Change
	It should have following features:-	No Change
	Integrated Heating insufflation tube for heating the Co2 gas up to patient body temperature.	Heating insufflation tube for heating the Co2 gas up to patient body temperature or somke evacualtion technology should be there
	Innovative sensitive mode for sensitive area such as pediatric application with safety limits in the pressure up to maximum 15 mmhg and flow range up to maximum 45ltr/min or more.	No Change
	High flow mode with flow performance up to 45 ltr/min.	No Change
2	Individually programmable procedure list for starting device with personal presets.	No Change
	Easy and intuitive use with user friendly colour touch screen for easy and precise setting of set values for pressure and flow and of insufflation mode, as well as for clear display of corresponding set values and actual values.	No Change
	Optical and acoustic alarm signals in the event of patient overpressure.	No Change
	Fully automatic electronically controlled gas refill.	No Change
	Safety system:- constant monitoring of intra abdominal pressure, any overpressure is reduced immediately.	No Change
	Applicable for use in laproscopy, in Thoracoscopy in proctology (forTransanal Endoscopic operationals) and for endoscopy of the upper and lower gastrointestinal trac, as well as in cardiac surgery (open or endoscopically assisted cardiac surgery to assure an optional	No Change

air extrusion and minimizing risk of postoperative wound infection- for minimally invasive cardiac surgery e.g. mitral valve surgery) and in vascular surgery(Endoscopic vessel harvesting)	
Control via Realistic user interface.	No Change
Should be supplied with Internal or External Smoke evacuation Unit	No Change
US FDA /European CE (Issued by a notified body) approved Model should be offered.	USFDA/European CF (issued by notified body)/Declaration of conformity to EC and ISO 13485
Technical Specifications:-	No Change
Gas flow 0 to 45 ltr/min or higher	No Change
Pressure 0 to 25 mmHg or higher	No Change
High flow mode (0 to 45 ltr/min)	No Change
Sensitive mode pressure 15 mmhg& flow sensitive application.	No Change
Electronic control and colour touch screen/touch keypad.	No Change
Following data are displayed on touch screen.	No Change
Set value pressure (0 to 25 mmHg)	No Change
Current patient pressure.	No Change
Current patient pressure	No Change
Set value gas flow (0 to 45 ltr/min)	No Change
Current gas flow	No Change
Gas Consumption (0.999 1)	No Change
Status of gas heating	No Change
Power supply 220 V AC 50 Hz	No Change
4K Camera Systems	No Change
1) 4 k Camera system and all compatible instrument with 4K system	No Change
The system should be truly Digital 4K endoscopic video camera. The system should have the maximum Resolution of 3840 X 2160 pixels. Progressive scan and the consistent use of 16 9 formats for input & output to guarantee genuine 4K	No Change
The system should have facility of optical or Digital Zoom lens to enhance the quality of image size and cross specialty usage of the camera system, regardless of the telescope uses.	No Change
Optional:-	

	USB port for capturing FULL HD video/HD stills in External USB drive and direct interface of USB recording device from the camera head.	OptionalUSB port for capturing FULL HD video/HD stills in External USB drive and direct interface of USB recording device from the camera head.
	Technical Specifications:	
	Image sensor: 3CCD or 3 chip CMOS progressive scan.	CCD/CMOS Autoclavable camera head
	Pixel: 3840 X 2160	No Change
	AGC: Microprocessor controlled.	No Change
	Lens: It should be optical Zoom lens f=13 to 29 mm or Digital Zoom 0-2 X	No Change
	Minimum light Sensitivity as per 4 K resolution.	No Change
	Control buttons : 2 or more (freely programmable)	No Change
	video out put 2x DVI-D or Out put 1x3g SDI out Put or 2 x HDMI or as per 4 k system out put	video out put 2x DVI- D or Out put 1x3g SDI out Put or 2 x HDMI or as per 4 k system out put Or 12G SDI Output
	Input: Keyboard input for character generator or touch screen	No Change
	Power supply 220 VAC 50 Hz.	No Change
	US FDA/ European CE (issued by a notified body) approved Model should be offered.	USFDA/European CE (issued by notified body)/Declaration of conformity to EC and ISO 13485
	3. 4k Medical Grade Monitor	No Change
	The monitor should have	No Change
	4 K 30 inches or more LED monitor with resolution of 3840 X 2160 Screen Diagnal	No Change
	Should have the facility of PIP mode.	No Change
	Specification	No Change
3	4K Monitor with stand/hanged on trolley size 30" or more	No Change
	Power supply 100-240 VAC	No Change
		2* DVI-D Or 3G SDI
	2* DVI-D 3G SDI 1* S video composite 1*RGBNGA.1* RS 232, 1*RJ 45 interface	1* S video composite 1*RGBNGA.1* RS 232, 1*RJ 45 interface
		Or 3G SDI or 12G SDI

	OR	
	Video Inputs: DVI Port -1, HDMI Port -2, RS232-1 & USB-1 OR as per 4 K Standard	No Change
	Video Outputs: 1* DVI, 1* 3G SDI. 1*S-Video Or Through USB 4 outputs via USB Video Outputs: 1*DVI, 1* 3G SDI. 1*S- video or Through USB 4 outputs via USB.	No Change
	4)LED 300 with fibre optical cable	3)LED 300 with fibre optical cable or equivalent xenon light source
	Lamp type: LED 15V 300 watt or more.	No Change
	Color Temperatures 5000DK and above.	No Change
4	Light intensity adjustment:- continuously adjustable either manually or automatically by cameras video output signal.	No Change
	Should be supplied with Diameter 4.8mm ±5% Length 300cm or more	No Change
	Certified to :- USFDA/European CE (with a notified body).	USFDA/European CE (issued by notified body)/Declaration of conformity to EC and ISO 13485
	IMAGE /VIDEO RECORDING AND DATA ARCHIVING SYSTEM (4K)	No Change
	State of the art user friendly Medical grade system (certified to be used in OT) offered with following features.	No Change
	User should have full control of the system from the sterile field via camera head buttons, optional touch screen, optional foot switch.	No Change
	Still images and videos (optional with audio) in 4K FULL HD water mark feature intelligent adaptive storage management.	No Change
5	Storage Location is freely definable and configurable.	No Change
	Storage on Internal Memory 1 TB or more .External Hard disk shall be supplied separately (2 TB)	No Change
	Automatic storage in the background to reduce the time between the interventions, Easy management and overview of open/automatic save processes.	No Change
	Import of patient data via keyboard or Touch Screen .	No Change
	Playback 4K content on separate monitor	No Change
	Integrated the file viewer for still images, videos and checking from diverse data sources.	No Change
	Structured and clear user guidance, optimized for touch screen control.	No Change
	Scalable range of functions:	No Change
	Low noise generation and last system start due to SSD-technology.	No Change
	Should have seamless USB silicone keyboard or touch pad Or Touch screen to enter details.	No Change

	Touch screen 6 to 12".	Touch screen 4 to 12".
	Input voltage :- 100-240 VAC	No Change
	Input frequency: 50-60 Hz	No Change
	Power output: 200 to 350 Watt.	No Change
	Tower output: 200 to 350 watt.	No Change
	Internal memory: SSD (70GB) I HDD (1 TB)	No Change
	Memory RAM : 8GB	No Change
	Conectors: 3x1 GB Ethernet (RJ 45), 6Xusb 2.0, 2x USB 3.0	No Change
	Image format: BMP,JPG,2000.	No Change
	Video format MPEF-4,MPEG-2 MOV	No Change
	Video signal inputs: 2x DVI-D	No Change
	Color system : PAL NTSC	No Change
	Resolution of Still images 3840X2160	No Change
	Resolution of Video should be 3840X2160	No Change
	System should have DICOM Facility & PACS Compatibility	No Change
	Endoscopic Trolley	
	Equipment cart, rides of 4 antistatic dual wheels equipped with locking brakes, central beam with integrated electrical sub distributor switch 6 sockets grounding plugs, modular in nature (should be able to add shelves and components later if required) for operation theatre use, from OEM, or marketed by OEM	No Change
	C02 cylinder holder	No Change
	Monitor holding arms (lateral)	No Change
	OEM trolly for this equipment should be offered	No Change
	Hand Instruments	
6	Telescopes:	
	a. Forward- oblique Telescope 30 degree enlarged view diameter 10mm. Length 31 cm \pm 5% autoclavable fiber optic light 4K HD telescope transmission incorporated -02 nos.	No Change
	b. Forward - oblique 4K HD Telescope 30 degree enlarged view diameter 5mm. Length $29 \pm 5\%$ autoclavable fiber optic light transmission incorporated. Connection for fiber optic light cable offset by 90degree- 02 nos.	No Change
	c. Straight forward 4K HD telescope 0 degree enlarged view diameter 100 length 31 cm \pm 5% autoclavable fiber optic light transmission incorporated -02 nos.	No Change
	LAPROSCOPLE DISSECTING & GRASPING FORCEPS	No Change
	1. Three piece laparoscopic autoclavable KELLY dissecting and Grasping Forcep. 360 degree rotational sheeth, with connector pin for unipolar coagulation size 5 mm. length 33-36 cm long (02 nos.) double action jaws, with ergonomic plastic handle with larger contact area at the finger ring to avoid pressure sores, can be dismantled with the press of a button.	No Change
	2. Three piece laparoscopic autoclavable CROCE-OLMI Grasping forceps360 degree rotational sheeth, size 5mm. length 33-36cm	No Change

(02nos.) double action jaws ergonomic metal handle with plastic finger rings with larger contact area at the finger ring to avoid pressure sores can be dimantied with the press of button.	
3. Three piece laparoscopic autoclavable Bowel Gasping forceps double action jaws, fenestrated, 360 degree rotational sheeth, size 5mm length 33-36cm (02 nos.) double action jaws, ergonomic metal handle with plastic finger rings with larger contact area at the finger ring to avoid pressure sores, can be dismantled with the press of a button.	No Change
4. Three piece laparoscopic autoclavable Right Maryland dissector/Forcep, double action jaws fenestrated, 360 degree rotational sheeth, size 5 mm, length 33-36 cm long double action jaws. Ergonomic metal handle with plastic finger rings with larger contact area at the finger ring to avoid pressure sores, can be dismantied with the press of a button (02 nos.)	No Change
5. Three piece laparoscopic autoclavable Maryland dissector/Forceps, double action jaws, fenestrated, 360 degree rotational sheeth, size 5 mm, length 33-36 cm. long, double action jaws, ergonomic metal handle with plastic finger rings with larger contact area at the finger ring to avoid pressure sores can be dismantled with the press of button (02 nos.)	No Change
6. Three piece laparoscopic autoclavable ANVIL Grasping forcep, double action jaws, fenestrated, 360 degree rotational sheeth, size 5 mm length 33-36 cm, long double action jaws, ergonomic metal handle with plastic finger rings with larger contact area at the finger ring to avoid pressure sores can be dismantled with the press of a button (02 nos.)	No Change
7. Three piece laparoscopic autoclavable MANHES Grasping forcep with hemostat style ratchet, duck bill 360 degree rotational sheeth with connector pin for unipolar coagulation size 5 mm length 33-36 cm, long single action jaws, ergonomic metal handle with larger contact area at the finger ring to avoid pressure sores can be dismantled with the press of a button.	No Change
8. Three piece laparoscopic autoclavable GLAW Grasping forcep with ratchet 2x3 teeth, 360 degree rotational sheeth size 10mm length 33-36 cm long single action jaws, with ergonomic metal handle can be dismantled with the press of a button (02 nos.)	No Change
9. Three piece laparoscopic autoclavable curved METZENBAUM scissors, 360degree rotational sheeth with connector pin for nipolar coagulation m size 5mm length 33-36cm long double action jaws with ergonomic plastic handle with larger contact area at the finger ring to	No Change
avoid pressure sores can be dismantled with the press of a button (02 nos)	
10. Three piece laparoscopic autoclavable Hook scissors, 360 degree rotational sheeth, with connector pin for unipolar coagulation size 5mm length 33-36 cm long double action jaws with ergonomic plastic handle with larger contact area at the finger ring to avoid pressure sores, can be dismantled with the press of a button (02 nos.)	No Change

11. Ergonomic plastic Handle with larger contact area at the finger rings with connector pin for unipolar coagulation with or without ratchet, compatible with above asked instruments (02 nos)	No Change
12. Dissecting Electrode with exchangeable electrode L-tip autoclavable ergonomic handling size 5 mm length 33-36 cm, with connector pin for unipolar coagulation (02 nos)	No Change
13. Spatula electrode Size 5 mm & length 33-36 cm (02 nos)	No Change
14. Unipolar HF Cord (05 nos)	No Change
15. Nathanson Liver Retractor small surface area, diameter 5mm (02nos)	No Change
16. Nathanson Liver Retractor Medium surface area diameter 5 mm (02nos)	No Change
17. Nathanson Liver Retractor large surface area diameter 6 mm-(02 nos)	No Change
18. Nathanson Lever Retractor with all atachments	No Change
19. Fascial closure instrument for subcutaneous ligature of trocar incisions, size 2-2.8mm length 12 to 17 cm (02 nos)	No Change
20. Satinsky Laproscopic clamp size of jaws 10cm-11cm depth of jaws 2.5 cm straight sheeth with axial handle ring ratchet with safety locking device 10mm length 30cm (02 nos)	No Change
21. Satinsky Laproscopic clamp size of jaws 8 cm depth of jaws 2 cm straight with axial handle ring ratchet with safety locking device 10mm length 30cm (02 nos)	No Change
22. Vascular clamp Applicator 10mm, 32 cm for use with deployable vascular clamps (02 nos)	No Change
23. Vascular clamp single action jaws, length of jaws, 5cm, size 10mm, total length 11 cm for user with vascular clamp applicator (02 nos)	No Change
24. Vascular clamp, parallel action jaws, length of jaws 5cm size 10mm total length 13 cm for use with vascular clamp applicator.	No Change
25. Bowl forcep- (02 nos)	No Change
Trocar &cannula:	
1. Cannula size: 10-11 mm diameter & 12-13mm with thread and rotating insufflations, should have multifunctional valve to prevent damage of sharp instruments and tip lens while passing through the cannula valve. It should have stopcock for C02 insufflation. The working length of the cannula should be $105mm$ (5 nos = 4+1)	No Change
2. Cannula size size 5.5-6 diameter with thread and rotating insufflations. Should have multifunctional valve to prevent damage of sharp instruments and tip lens while passing through the cannula valve. it should have stopcock for C02 insufflation. The working length of the cannula should be 105mm (5nos)	No Change
3. Additional:- Please be kind to add safety trocar -01 no to be used with 11 mm sheath cannula	No Change
4. Double reducer: 13.5/10 & 13.5/5mm – (5 each)	No Change

5. Reducer: 10/5mm-(05nos)	No Change
6. Laparoscopic High-frequency needle for splitting &coagulation, puncture in PCOD, insulated with connector pin for unipolar coagulation 5mm, 36mm=02.	No Change
7. Knot-tier for extra-corporeal knotting, 5mm, 36cm=02	No Change
8. Papation probe with cm-markings ,5mm 36cm=02	No Change
9. Rotating dismantling in three parts (handle outer tube & working insert) Laparoscopic MESO-OVARAIAN forceps, with insulation handle with hemostat-type ratchet & pin connector for unipolar coagulation 5mm, 33-36cm=02	No Change
10. Laparoscopic Myoma fixation instrument screw-shaped 5mm=02.	No Change
Veress Needle	
Veress pneumoperitoneum with spring loaded blunt inner cannula ,LUER-Lock autoclavable dimeter 2.1mm working length 10-18 cms(05 nos)	No Change
Injection Needle	
Injection needle , LUER-lock diameter 1.2mm size 5mm length 36cm (05 nos.)	No Change
Suction and Irrigation Tube	
Suction and Irrigation tube anti-reflex surface with two-way stopcock for single hand control size-5 mm length 36cm (10 nos)	No Change
LAPAROSCPIC NEEDLE HOLDERS	
Needle holder with tungsten carbide insert dismantling in to three part namely outer tube handle and inserts, ergonomic pistol handle with disengageable ratchet jaw curved to left OR in single piece size 5mm length 33cm for user with suture material size 0/0 to 7/0 (06nos)	No Change
Macro needle holder with tungsten carbide insert, dismantling in to three parts namely outer tube handle and inserts, ergonomic pistol handle with disengageable ratchet jaw curved to left OR in single piece size 5mm length 33cm for user with suture material size 0/0 to 7/0 (06nos)	No Change
Laparoscopic Bipolar Forceps	
Three piece laparoscopic Bipolar coagulating Grasping Forceps with overload tissue protection, CLERMONT –FRRRAND MODEL, wide jaws with connector pin for bipolar coagulation 360degree rotational sheeth size 5mm length 33-36cm long, single action jaws ergonomic plastic handle with larger contact area o can be dismantled with the press of a button (02 nos.)	No Change
Three piece laparoscopic Bipolar KELLY dissecting & Grasping Forceps with overload tissue protection, CLERMONT –FRRRAND MODEL, wide jaws with connector pin for bipolar coagulation 360degree rotational sheeth size 5mm length 33-36cm long, single action jaws ergonomic plastic handle with larger contact area o can be dismantled with the press of a button (02 nos.)	No Change
Clip Applicator :05	No Change

	Clip applicator 10mm rotable, Length 36cm for application of clip LT-300.		No Change
	Clip Applicator :05		No Change
	Large clip applicator dismanteable rotating size : 10mm, l for Titanium.	No Change	
	Titanium clips: 50 Boxes 24 clip each.		No Change
	Titanium Clips medium large & large box with 16 sterile cartridges 10 clips eagh for use with clip applicator. All instruments should be USAFDA/European CE (Issued by notified body), compatible to all system.		No Change
			All instruments should be Certification USFDA/European CE (issued by notified body)/Declaration of conformity to EC and ISO 13485, compatible to all system.
	Name of Equipment :- Hystoroscopy System with Camer		
SI. No	Technical Specification as per tender	Amendment	
	Camera control unit		
	The system should be B5:B10aximum Resolution of 3840 X 2160 pixel and progressive scan to guarantee genuine 4K.	No Change	
	The system should have facility of 2x Digital Zoom or more	No Change	
	The system should have facility for capturing 4K UHD HD Still and FULL HD Video in Extern USB drive (Optional).	No Change	
	· Native 4 k resolution of 3840 X 2160	No Change	
4	· Picture in Picture of visualization modes.	No Change	
1	· Automatic Manual adjustment of light intensity of light source.	No Change	
	Technical Specifications:		
	Video output2 x DVI –D output/1 x3G-SDI output or 2 x HDMI or as per 4 k system out put.	No Change	
	Input keyboard input for character generator (optional)	No Change	
	Power supply:200-240 VAC 50/60 Hz		No Change
	Certification- USFDA/European CE (issued by notified body) Declaration of conformity according to the EU MDR 2017) and ISO 13485	(issued Declara	ation of conformity to EC and ISO 13485

	2. 3CCD/3 CMOS Autoclavable CAMERA HEAD	CCD/ CMOS Autoclavable Camera Head
	Pixel: 3840 X 2160 Pixel	
2		No Change
2	AGC Microprocessor controlled	No Change
	Optical Zoom lens f=13-29 mm or Optical zoom lens f=15-32 mm	No Change
	Control buttons: min 2 freely Programmable	No Change
3	3. Should be supplied with 4K HD scope for 4K Camera	No Change
4	4. Should be 4K medical grade Monitor size not less than 30"	No Change
	The monitor should have If should have a facility to be connected to 4K and 3D or sperate Monitor should be supplied for 4K and Color space –BT 2020 emulation	No Change
	Aspect ratio: 16:9	No Change
	Size-30 inch	Size-30 inch or more
	Effective Resolution: 3840 X 2160Pixel	No Change
	Inputs: 1Xdp 1.2 2XDVI-D 4 x 3G-SDI/1X 12G SDI	No Change
	Outputs: 1x DVI-D4 x 3G-SDI/1 X 12 GSDI	No Change
	Certification-USFDA/European CE (issued by notified body/Declaration of conformity according to the EU MDR 2017) and ISO 13485	Certification- USFDA/European CE (issued by notified body) Declaration of conformity according to EC and ISO 13485
	5. LED/Xenon Light source 300W with Fiber Optic cable	No Change
	· Should have touch display which provides and intuitive & user friendly interface that directly displays relevant data.	No Change
	· Cold Light Fountain LED Light source	No Change
	· Lumens: 2100 and above	No Change
	· Color Temperature 5000K or above.	No Change
	· Light outlets-1	No Change
5	· Lamp LED life of approx. : 30,000 hrs.	Lamp LED life of approx.: 30,000 hrs. Or In Case of Xenon light Source 5 Spare Lamps Should be Provided
	· 4.8 mm Fiber Optic Cable and 300cm Long	No Change
	Certification-USFDA/European CE (issued by notified body/Declaration of conformity according to the EU MDR 2017) and ISO 13485	Certification- USFDA/European CE (issued by notified body) Declaration of conformity according to EC and ISO 13485

6	6. IMAGE/ VIDEO RECORDING AND DATA ARCHIVING SYSTEM	No Change
	· State of the art user friendly Medical grade system (Certified to be used in OT) should be offered with following features.	No Change
	· User should have full control of the system from the sterile field via camera head buttons optional touch screen optional foot switch.	No Change
	· Still images and videos (optional with audio) in HD/4K.	No Change
	· Internal memory should be 1 TB and extra 1 TB.	No Change
	· Playback of HD or 4K content.	No Change
	It should be touch screen and 5-12.5 inches	It should be touch screen and 4-12.5 inches
\Box		
	Certification-USFDA/European CE (issued by notified body/Declaration of conformity according to the EU MDR 2017) and ISO 13485	Certification- USFDA/European CE (issued by notified body) Declaration of conformity according to EC and ISO 13485
	7. Imported Endoscopic Trolley	No Change
a	Endoscopic Trolley compatible with the above system from the same manufacturer/Marketed by the same company or OEM should be provided.	No Change
	SPECIFICATION FOR HYSTEROSCOPE SET WITH RESECTOSCOPE	No Change
	Operating and contact – Hysteroscope forward oblique Telescope 30 degree enlarged view magnification 1x, 30x diameter 4.0 mm , length 30cm autoclavable, fiber optic light transmission incorporated, Forwarded oblique Telescope 30 degree enlarged view, diameter 4.0mm, length 30cm, autoclavable, fiber optic light transmission incorporated.	No Change
	Forwarded oblique Telescope 30 degree enlarged view, diameter 2.7-3.0 mm length 30cm, autoclavable, fiber optic light transmission incorporated.	No Change
	Telescope sheath for diagnostic continuous irrigation size 4.5,5.4 mm outer sheath and 3.8,3.9 mm inner sheath for user 2.0-3.0mm hysteroscope telescope.	Telescope sheath for diagnostic continuous irrigation size 4.5 - 5.5 mm outer sheath and 3.8 - 3.9 mm inner sheath for user 2.0,3.0mm hysteroscope telescope or integrated sheath for using with 2.0, 3.0 mm hysteroscope

Continuous irrigation flow operating sheath inner size between 4.8-5.0mm and outer size between 5.5-5.6mm having operating channel 5Fr to be used with 2.9-3.0mm telescope with LEUR lock and inflow and outflow channel	No Change
Examination sheath diameter 5.0-5.1mm to be used with 4mm telescope with 1 LUER lock adapter.	No Change
Continuous flow Examination sheath, inner size diameter 5.2-5.3 & outer diameter size 6.2-6.3 mm to be used with 4mm telescope with 1 LUER lock adaptor.	Deleted
Continuous flow operating sheath inner size 5.4-5.5mm &outer size 6.0-6.1mm with 5Fr. Channel for operating with 1 stopcock and 1LUER Lock adapter	No Change
Continuous Flow operating sheath inner size 5.4-5.5mm & outer size 6.0-6.1mm with 5Fr. Channel for operating with 1 stock cock and 1LUER Lock adaptor.	No Change
Scissors blunt tips 5 Fr. Length 34 cm single action jaws.	No Change
Scissors pointed jaws, 5Fr. Length 34cm single action jaws, semi-rigid.	No Change
Biopsy and Grasping forceps 5Fr. Length 34 cm double action jaws	No Change
Bipolar vaporization electrode, 5Fr. Length 36 cm	No Change
High Frequency cord with 4mm plug HF unit older models 300 cm	No Change
Bipolar High Frequency	No Change
Working Element set consisting of:	No Change
1 working element, 1 cutting Loop, angled, 1 coagulation —Electrode ball end 3cm, 1 coagulating Electrode ball end 5cm, 1 coagulating Needle Electrode angled, 2 High Frequency cord, 1 Protection tube for electrodes	No Change
Motion by means of a spring. The thumb support is movable return of the loop is controlled by the (thumb to be used with 4mm telescope)	No Change
Cutting loop 24 Fr. And Roller electrode 24Fr. 12 no. each.	No Change
Resectoscope sheath 26 Fr, including connection tubes for in-and outflow, 2 LUER –lock adapters 8mm oblique beak, fixed inner tube with ceramic insulation for user with working element.	No Change
Obturator for use with sheaths	No Change
Forward oblique Tele-scope 30degree 2.7-3.0 mm length 30-31 cm autoclavable fiber optic light transmission incorporated	No Change

Operating sheath size4.3-4.8 mm with channel for semi rigid 5Fr. Operating instruments with 1 stopcock and 1 LUER-Lock adaptor, for use with CF operating sheath.	No Change
Continuous –Flow operating sheath size 5mm with 1 stopcock and 1LUER-Lock adaptor for use with operating sheath	No Change
Scissors blunt, single action jaws semirigid 5 Fr. Length 34 cm.	No Change
Pointed single action jaws semirigid 5Fr. 34cm	No Change
and Grasping Forceps Double action jaws semirigid 5Fr. Length 34 cm punch through cutting single action jaws semirigid 5Fr. Length 34 cm.	No Change
Biopsy spoon forceps, double action jaws semirigid 5Fr. Length 34cm.	No Change
Fixation Instrument semirigid5Fr. Length 34cm.	No Change
Polypectomy Loop unipolar 5Fr. Length 34cm.	No Change
Needle Electrode unipolar 5Fr. Length 34cm.	No Change
Bipolar Vaporization electrode semirigid5Fr. Length 36cm.	No Change
Telescope 12/30degree o 2.7-2.9 mm, length 30 cm autoclavable fiber optic light transmission incorporated, color code black.	Telescope 12/30degree, 2.7-2.9 mm, length 30 cm autoclavable fiber optic light transmission incorporated, color code black.
Resectcope sheath including connecting tube for in-and outlow for continuous irrigation and suction 0 7mm oblique beak rotable sheath with ceramic insulation for use with working element.	Resectscope sheath including connecting tube for in-and outflow for continuous irrigation and suction $0-7$ mm $/$ 22 Fr. \pm 5% oblique beak rotatable sheath with ceramic insulation for use with working element.
Resectcope sheath including connecting tube for in-and outlow for continuous irrigation and suction 0 7mm oblique beak fixed inner sheath with ceramic insulation for use with working element color code white.	Resectscope sheath including connecting tube for in-and outflow for continuous irrigation and suction $0-7~\text{mm}/22~\text{Fr.}\pm5\%$ oblique beak fixed inner sheath with ceramic insulation for use with working element color code white.
Working Element set consisting of working Element cutting Loop angled coagulation Electrode pointed coagulating Electrode ball end 0.3mm cutting by means of a spring. The thumb support is movable in rest position the electrode tip is inside the sheath. High Frequency cord protecting Tube.	Working element set consisting of working element cutting loop angled coagulation electrode pointed coagulating electrode ball end cutting by means of a spring. The thumb support is movable in rest position the electrode tip is inside the sheath. High frequency cord protecting tube.

Environmental factors	
1. 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.	No Change
2. The unit shall be capable of operating continuously in ambient temperature of 20-30 degree C and relative humidity of 15-90%	No Change
3. The unit shall be capable of being stored continuously in ambient temperature of 0.50degree C and relative humidity of 15-90%	No Change
Power supply	
1. Power input to be 220-240VAC; 50Hz fitted with Indian Plug	No Change
2. Certification-USFDA/European CE (issued by notified body/Declaration of conformity according to the EU MDR 2017) and ISO 13485	Certification- USFDA/European CE (issued by notified body) Declaration of conformity according to EC and IS 13485
3. Shall be certified to the meeting safety standard IEC 60601-2-18 particular requirements for the safety of endoscopic equipment.	No Change
4. All instrument should be USFDA/European CE (issued by notified body)/Declaration of conformity according to the EU MDR 2017) and ISO 13485 all item should be compatible.	All instrument should be USFDA/European CE (issued by notified body) Declaration of conformity according to EC and ISC 13485 approved, all item should be compatible.
Documentation	•
1. User/ Technical/Maintanance manuals to be supplied in English.	No Change
2. Compliance Report to be submitted in a tabulated and point wise manner clearly mentioning the page/para number of original catalogue/data sheet. Any point, if not substantiated with authenticated catalogue/manual, will not be considered.	No Change
3. Certificate of calibration and inspection.	No Change
4. List of Equipments available for providing calibration and routine preventive maintenance support as per manufacturer documentation in service/technical manual.	No Change
5. Log Book with instructions for daily, weekly, monthly and quarterly maintenance checklist. The job description of the hospital technician and company service engineer should be clearly spelt out.	No Change
Additional:	
	N. C1
Cutting loops for TCR-20Coagulating Loops-5	No Change No Change

Added- Hysteroscopy pump for intra uterine fluid management	No Change
· It should have Electronic digital suction/irrigation pump with color touch LCD screen display.	No Change
· It should have precise presetting of flow and pressure of suction and irrigation parameters via touch keys.	No Change
· It should have built in low noise suction pump to allow simultaneous suction -irrigation process.	No Change
· It should have multiple utility mode like laparoscopy, Hysteroscopy, Orthoscopy, Urology etc.	It should have multiple utility mod like Laparoscopy, Hysteroscopy Orthoscopy, Urology etc. (Optional).
It should have irrigation pressure should be 10-400mmHg or more.	No Change
· It should have auto cut off facility for the preset amount of the fluid.	No Change
· It should have 3 audio visual alarm for 3 preset stage of the consumed fluid.	It should have 3 audio visual alarr for 3 preset stage of the consume fluid (Optional).
· It should have preset multiple hysteroscopy user setting for different intra uterine surgeries.	No Change
· It should display of actual/real time pressure and consumed fluid to ensure safety.	No Change
· It should have complete fluid management system with measurement of consumed fluid & real time measurement of return fluid.	It should have complete fluid management system with measurement of consumed fluid & real time measurement of return fluid (Optional).
• It should give the display of real time deficit or absorption of fluid in body during surgery.	Deleted
· It should give alarm for deficit/absorbed fluid over safe range, also should have user settable safe range as per surgical requirements.	It should give alarm for deficit / absorbed fluid over safe range, als should have user settable safe rang as per surgical requirements (Optional).
· It should have option for flush out the liquid.	It should have option for flush out the liquid (Optional).

· It should have facility to select the fluid (saline/glycine).	No Change
. It should have flow rate 100-1000 ml /min or More.	No Change
· It should have display of total volume consumed.	No Change
· It should have audio visual alarm for over usage of fluid.	No Change
· It should have facility to use different fluids.	No Change
· It should have suction vacuum 75Kpa or More.	No Change
· It should have supplied with 3 liter jar 02 nos.	No Change
· It should have supplied with Y shaped irrigation tubing set.	No Change
· It should have supplied with pressure sensor 05 nos, cartridge filter 05 nos.	No Change
• It should have supplied with trolley with bottle stand and suction bottle holder.	No Change
· Certification-USFDA/European CE (Issued by notified body/Declaration of conformity according to the EU MDR 2017) and ISO 13485	Certification-USFDA/European CE (Issued by notified body/Declaration of conformity to EC and ISO 13485