

**Amendment No. 02****Sub: Amendment to the referred tender enquiry**

**Ref.:** Tender Enquiry Document HITES/PCD/PMSY-IV/25/Mix/2022-23 dated 12-08-2022 and its Amendment No. 01 dated 18-Aug-2022.

Following changes are being incorporated in the tender:

**SECTION I**  
**NOTICE INVITING TENDER (NIT)**

For:

Sl. No.	Tender ID	Short Description of goods	Dept.	Qty. (Nos.)	Bid Security (EMD) (₹)	Tender Processing Fee incl. GST (₹)
2	2022_HLL_125318_2	Extracorporeal Shock Wave Lithotripter (ESWL)	URLG	16	96,00,000	8,850

Tender Timeline:

Sl. No.	Description	Schedule
1.	Last date and time of online submission of tender	20-09-2021 at 01:00 PM
2.	Last date and time of physical submission of Tender processing Fee, any other document specified in the Bidding Document	21-09-2021 at 02:00 PM
3.	Date & time of online tender opening	21-09-2021 at 02:30 PM

Read As:

Sl. No.	Tender ID	Short Description of goods	Dept.	Qty. (Nos.)	Bid Security (EMD) (₹)	Tender Processing Fee incl. GST (₹)
2	2022_HLL_125318_2	Extracorporeal Shock Wave Lithotripter (ESWL)	URLG	16	<b>1,44,00,000</b>	8,850

Tender Timeline:

Sl. No.	Description	Schedule
1.	Last date and time of online submission of tender	<b>17-10-2021 at 01:00 PM</b>
2.	Last date and time of physical submission of Tender processing Fee, any other document specified in the Bidding Document	<b>18-10-2021 at 02:00 PM</b>
3.	Date & time of online tender opening	<b>18-10-2021 at 02:30 PM</b>

**SECTION II**

**GENERAL INSTRUCTIONS TO TENDERERS (GIT)**

:For	Read As
13.4.2 For goods offered from abroad, the prices in the corresponding price schedule shall be entered separately in the following manner a) The price of goods quoted FOB/FCA port of shipment, as indicated in the List of Requirements and Price Schedule;	13.4.2 For goods offered from abroad, the prices in the corresponding price schedule shall be entered separately in the following manner <b>a) Deleted;</b> b) Price of goods quoted CIP (name port of destination) in India as indicated in the List of

:For	Read As
<p>b) Price of goods quoted CIP (name port of destination) in India as indicated in the List of Requirements, Price Schedule and Consignee List</p> <p>c) The charges for Insurance (local transportation and storage), custom clearance, forwarding and handling would be extended and borne by the Supplier from ware house to the consignee site for a period including 3 months beyond date of delivery. Loading/Unloading and other local costs incidental to delivery of the goods to their final destination as specified in the List of Requirements and Price Schedule;</p> <p>d) The charges for Incidental Services, as in the List of Requirements and Price Schedule;</p> <p>e) The prices of Site Modification Work (if any), as mentioned in List of Requirements, Technical Specification and Price Schedule; and</p> <p>f) The price of annual CMC, as mentioned in List of Requirements, Technical Specification and Price Schedule.</p>	<p>Requirements, Price Schedule and Consignee List</p> <p><b>c) The charges for Insurance (local transportation and storage) would be extended and borne by the Supplier from ware house to the consignee site for a period including 3 months beyond date of delivery.</b> Loading/Unloading and other local costs incidental to delivery of the goods to their final destination as specified in the List of Requirements and Price Schedule ;</p> <p>d) The charges for Incidental Services, as in the List of Requirements and Price Schedule;</p> <p>e) The prices of Site Modification Work (if any), as mentioned in List of Requirements, Technical Specification and Price Schedule; and</p> <p>f) The price of annual CMC, as mentioned in List of Requirements, Technical Specification and Price Schedule.</p>
<p>13.5.3 Customs Duty: The Purchaser will pay/reimburse the Customs duty wherever applicable upon submission of documentary evidence.</p>	<p>13.5.3 Customs Duty: <b>Deleted.</b></p>

**SECTION VII**  
**TECHNICAL SPECIFICATIONS**

<b>Item No 1 Ultrasonic Cutting &amp; Coagulation, Advanced Radio Frequency/ Bipolar Energy System (GNS)</b>		
<b>Tender spec Para</b>	<b>TENDER SPECIFICATION</b>	<b>READ AS</b>
A.2	Should have the ability to select hand switch or footswitch activation or both for ultrasonic and advanced RF energy instruments and the ability to change selection during use can seal and transect vessel upto 7mm with system feedback mechanism for better patient safety.	Should have the ability to select hand switch or footswitch activation or both for instruments and the ability to change selection during use. The system provided should be able to seal and transect vessels up to 7mm by <b>a) pure ultrasonic energy alone OR b) ultrasonic energy in combination with RF/HF</b> with system feedback mechanism for better patient safety.
A.8	Should be able to power energy instruments with microprocessor controlled bipolar electrosurgical radiofrequency technology with a sinusoidal forced impedance output.	Should be able to power energy instruments with microprocessor controlled bipolar electrosurgical radiofrequency technology with a <b>sinusoidal / Quasi sinusoidal</b> forced impedance output.
C.1	Generator cart - 1 No.	<b>OEM</b> Generator cart - 1 no
C.4	Ultrasonic 5 mm Laparoscopic hand	<b>Ultrasonic/Integrated ultrasonic &amp; RF</b>

<b>Item No 1 Ultrasonic Cutting &amp; Coagulation, Advanced Radio Frequency/ Bipolar Energy System (GNS)</b>		
<b>Tender spec Para</b>	<b>TENDER SPECIFICATION</b>	<b>READ AS</b>
	activated curved tip coagulating probe Quantity 2 Nos.	<b>energy</b> 5 mm Laparoscopic hand activated curved tip coagulating probe Quantity <b>10 Nos.</b>
C.5	Ultrasonic hand activated curved tip coagulating probe for open surgery: Quantity 2 Nos.	<b>Ultrasonic/Integrated ultrasonic &amp; RF energy</b> hand activated curved tip coagulating probe for open surgery: Quantity <b>10 Nos.</b>
C.6	Advanced RF/Bipolar 5 mm Laparoscopic hand activated curved tip coagulating probe: Quantity 2 Nos.	<b>Advanced RF/Bipolar or Integrated ultrasonic &amp; RF energy</b> 5 mm Laparoscopic hand activated curved tip coagulating probe: Quantity <b>10 Nos.</b>
C.7	Advanced RF/Bipolar hand activated curved tip coagulating probe for open surgery Quantity 2 Nos.	<b>Advanced RF/Bipolar or Integrated ultrasonic &amp; RF energy</b> hand activated curved tip coagulating probe for open surgery Quantity <b>10 Nos.</b>
BOQ.4	Ultrasonic 5 mm Laparoscopic hand activated curved tip coagulating probe - 2 nos	<b>Ultrasonic/Integrated ultrasonic &amp; RF energy</b> 5 mm Laparoscopic hand activated curved tip coagulating probe Quantity <b>10 Nos.</b>
BOQ.5	Ultrasonic hand activated curved tip coagulating probe for open surgery - 2 nos	<b>Ultrasonic/Integrated ultrasonic &amp; RF energy</b> hand activated curved tip coagulating probe for open surgery: Quantity <b>10 Nos.</b>
BOQ.6	Advanced RF/Bipolar 5 mm Laparoscopic hand activated curved tip coagulating probe - 2 Nos	<b>Advanced RF/Bipolar or Integrated ultrasonic &amp; RF energy</b> 5 mm Laparoscopic hand activated curved tip coagulating probe: Quantity <b>10 Nos.</b>
BOQ.7	Advanced RF/Bipolar hand activated curved tip coagulating probe for open surgery	<b>Advanced RF/Bipolar or Integrated ultrasonic &amp; RF energy</b> hand activated curved tip coagulating probe for open surgery Quantity <b>10 Nos.</b>
		<p><b>Added para:</b> Should have import/manufacturing license from Central licensing Authority or State licensing authority of CDSCO for Medical Devices and copy of valid license should be submitted for the quoted model</p> <p>In case the supplier has not yet obtained import/manufacturing license from CDSCO for the quoted model, proof of application for CDSCO medical device license to be submitted in the bid document and valid CDSCO license to be produced before award of contract.</p>

<b>Item No 2 Extracorporeal Shock Wave Lithotripter (ESWL)</b>		
<b>Tender spec Para</b>	<b>TENDER SPECIFICATION</b>	<b>READ AS</b>
2.1	Completely integrated system with Fluoroscopy and Ultrasound guided	Completely integrated system <b>where the shock wave module, fluoroscopy and patient table are</b>

Item No 2 Extracorporeal Shock Wave Lithotripter (ESWL)		
Tender spec Para	TENDER SPECIFICATION	READ AS
	stone localization and targeting along with digital documentation and patient data management system with data storage is required. The system should be compatible with available Hospital Information System.	<b>completely integrated.</b> The system should have Fluoroscopy and Ultrasound guided stone localization and targeting along with digital documentation, patient data management system and data storage. The system should be compatible with available Hospital Information System.
3.1.d	Penetration Depth minimum 150 mm or more	Penetration depth: <b>Minimum 170 mm or more</b>
3.2. e	Image Intensifier Size: 9 inches.	<b>Flat Panel detector 21x21 cms</b>
		<b>Added para:</b> 3.2.h Localization and targeting of stone using fluoroscopy should be fully motorized. The Anteroposterior to Orbital/ Craniocaudal movement and also Orbital/ Craniocaudal to Anteroposterior movement should be fully motorized
3.4	Patient Table System:	
i)	Fluoroscopy compatible motorized patient Table with Vertical, Longitudinal and lateral movements. Patient load capacity of app 150 Kg	Fluoroscopy compatible motorized patient Table with Vertical, Longitudinal and lateral movements. Patient load capacity of app 150 Kg. <b>Table should be from same OEM</b>
4.2	Should be compliant to ISO 13485: Quality systems - Medical devices - Particular requirements for the application of ISO 9001 applicable to manufacturers and service providers that perform their own design activities.	Manufacturer should have ISO 13485 certification issued from: Any Certification Bodies registered with NABCB under Medical Devices Quality Management System OR Any notified body registered with CDSCO OR Any 4-digit CE notified body
		<b>Added para:</b> 4.3. Should have import/manufacturing license from Central licensing Authority or State licensing authority of CDSCO for Medical Devices and copy of valid license should be submitted for the quoted model  In case the supplier has not yet obtained import/manufacturing license from CDSCO for the quoted model, proof of application for CDSCO medical device license to be submitted in the bid document and valid CDSCO license to be produced before award of contract.
SN	BOQ	
5	LED X ray display 2x6 ft or bigger - 2 Nos.	LED X ray display <b>2 x 5.4 ft. or bigger</b> - 2 Nos.

Item No 3 Ultrasound for Urology Applications		
Tender spec Para	TENDER SPECIFICATION	READ AS
5	System should have provision for integration with the <b>Da Vinci</b> Surgical Robot, in the OR with compatible transducer	System should have provision for integration with the Surgical Robot system, in the OR with compatible transducer
6	19" flat panel monitor should have swivel facility.	<b>19"ormore</b> flat panel monitor should have swivel facility.
20	Should have provision for PSA related calculations such as PSA density <b>and velocity</b>	Should have provision for PSA related calculations such as PSA density
22	System should be compatible with multi frequency convex array 4 to 14 MHz robotic drop in transducer. Transducer imaging should be controlled directly from surgeon's console and should have easy plug and play for seamless integration of images into <b>Davinci</b> surgical robot during Robotic assisted partial nephrectomies. Transducer should be fully immersible for easy sterilization and also compatible with standard sterilization methods like sterrad and steris systems	System should be compatible with multi frequency convex array 4 to 14 MHz robotic drop in transducer. Transducer imaging should be controlled directly from surgeon's console and should have easy plug and play for seamless integration of images into surgical robot system during Robotic assisted partial nephrectomies. Transducer should be fully immersible for easy sterilization and also compatible with standard sterilization methods like sterrad and steris systems
25	System should have <b>sterilizable</b> remote control so that surgeon can change ultrasound imaging parameters from sterile filed	System should have remote control so that surgeon can change ultrasound imaging parameters from sterile filed
28.c	4-14 MHz transducer for dynamic evaluation of central and posterior compartment of the pelvic floor to assess organ prolapse, sphincter disorders (Urinary and fecal incontinence), mesh and sling placement. Should have linear array with inbuilt mover which rotates 360 deg and should acquire 2D and 3D imaging data sets with no moving parts inside the patient. Transducer should have programmable start/stop button to activate the transducer, freeze and store image.	4-14 MHz <b>(+/- 1-2 MHz)</b> transducer for dynamic evaluation of central and posterior compartment of the pelvic floor to assess organ prolapse, sphincter disorders (Urinary and fecal incontinence), mesh and sling placement. Should have linear array with inbuilt mover which rotates 360 deg and should acquire 2D and 3D imaging data sets with no moving parts inside the patient. Transducer should have programmable start/stop button to activate the transducer, freeze and store image.
		<b>Added para:</b> 28.d. A high resolution intra operative laparoscopic four way deflectable transducer, which allows good organ contact and access to difficult to reach areas, and which can be used through normal laparoscopic ports ( 10-12mm) . The transducer should be fully immersible for easy sterilization

Item No 3 Ultrasound for Urology Applications		
Tender spec Para	TENDER SPECIFICATION	READ AS
		<p><b>Added para:</b> 32. Should have import/manufacturing license from Central licensing Authority or State licensing authority of CDSCO for Medical Devices and copy of valid license should be submitted for the quoted model</p> <p>In case the supplier has not yet obtained import/manufacturing license from CDSCO for the quoted model, proof of application for CDSCO medical device license to be submitted in the bid document and valid CDSCO license to be produced before award of contract.</p>

Item No. 4 Urology Workstation for Ultrasonic, Advanced Radiofrequency and Monopolar Energy		
Tender spec Para	TENDER SPECIFICATION	READ AS
A.6	Should be able to power ultrasonic energy instruments with 35KHz and above frequency, Monopolar cutting <b>300-400W</b> , Monopolar Coagulation: <b>100W or more</b> , Bipolar cutting 100W or more, Bipolar coagulation <b>100W or more</b> . [Monopolar and Bipolar should be underwater compatible]	Should be able to power ultrasonic energy instruments with 35KHz and above frequency, Monopolar cutting 300-400W, Monopolar Coagulation:100W or more, Bipolar cutting 100W or more, Bipolar coagulation <b>90W or more</b> . [Monopolar and Bipolar should be underwater compatible]
<b>B</b>	<b>FOOT SWITCH &amp; CABLE</b>	<u>FOOT SWITCH &amp; CABLE</u> Common Footswitch / Multiple footswitch for Monopolar, Bipolar and Ultrasonic should be provided
		<b>Added para:</b> Bipolar HF cable - 1 No
		<b>Added para:</b> Monopolar HF cable - 1 No
C.6	Monopolar accessories: Reusable forcep/pencil with reusable cable: 1no Electrode for monopolar pencil/forcep: 5 no Reusable patient plate with reusable cable: 1 no Reusable bipolar forceps with reusable cable: 1	Monopolar accessories: Reusable forcep/pencil with reusable cable : 1no Electrode for monopolar pencil/forcep: 5 no <b>Reusable patient plate with reusable cable: 1 no OR Disposable Split Type patient Plate/pad : 50 Nos.</b>  Reusable bipolar forceps with reusable cable: 1
		<b>Added para:</b> Should have import/manufacturing license from Central licensing Authority or State licensing

Item No. 4 Urology Workstation for Ultrasonic, Advanced Radiofrequency and Monopolar Energy		
Tender spec Para	TENDER SPECIFICATION	READ AS
		<p>authority of CDSCO for Medical Devices and copy of valid license should be submitted for the quoted model</p> <p>In case the supplier has not yet obtained import/manufacturing license from CDSCO for the quoted model, proof of application for CDSCO medical device license to be submitted in the bid document and valid CDSCO license to be produced before award of contract.</p>

Item No 6 Continuous Renal replacement therapy (CRRT)		
Tender spec Para	TENDER SPECIFICATION	READ AS
3.12	Should have Dialysate Flow rate: 100-2500 mL/Hr.	Should have Dialysate Flow rate: <b>100-8,000 mL/Hr or better</b>
4.3	Should be supplied with 10 sets of all essential accessories at no extra cost for 10 procedures	<p>Should be supplied with following accessories:</p> <p>Blood line set (Adult) : 50 Nos.                      Blood line set (Paediatric): 10 Nos.                      Haemofilters (Adult): 50 Nos.                      Haemofilters (Paediatric): 10 Nos.                      Replacement fluid bag: 100 Nos.                      Drain bags: 50 Nos.</p> <p><i>Note: Price of the above mentioned accessories should be quoted separately and which will be frozen during the warranty period. The Levied taxes will be as per prevailing rate as specified time to time by government.</i></p>
BOQ.2	Blood line set 10 Nos.	BOQ.2. Blood line set (Adult): 50 Nos. BOQ.3. Blood line set (Paediatric) : 10 Nos.
BOQ.3	Haemofilters 10 Nos	BOQ.4. Haemofilters (Adult): 50 Nos. BOQ.5. Haemofilters (Paediatric): 10 Nos.
BOQ.4	Ultra filtrate bags 10 Nos.	BOQ.6. Replacement fluid bag: 100 Nos. BOQ.7 Drain bags: 50 Nos.

**Note:**

- i. All other contents of the tender enquiry including terms & conditions remain unaltered.
- ii. Prospective Bidders are also advised to check the website regularly prior to the closing date and time of online submission of bids.
- iii. **For Tender IDs 2022\_HLL\_125318\_1, 2022\_HLL\_125318\_2, 2022\_HLL\_125318\_3, 2022\_HLL\_125318\_4 & 2022\_HLL\_125318\_6 only:**  
 TC compliance sheet v1.0 and Price bid format v1.0 is being uploaded on CPP Portal for necessary actions of interested Bidders.