29-09-2017

## **Amendment No. 09**

Sub: Amendment to the referred tender enquiry

Ref.: Tender Enquiry HITES/PCD/PMSSY-III/07/CTVS/2017-18 dated 08-06-2017 read with Amendment No. 01 dated 03-07-2017, Amendment No. 02 dated 10-07-2017, Amendment No. 03 dated 20-07-2017, Amendment No. 04 dated 25-07-2017, Amendment No. 05 dated 27-07-2017, Amendment No. 06 dated 03-08-2017, Amendment No. 07 dated 29-08-2017 & Amendment No. 08 dated 29-08-2017

The following changes have been incorporated in the referred tender enquiry.

# Section I Notice Inviting Tender

## **Existing:**

SI. No.	Rfx No.	Item Description	Qty.	Tender Processing Fee (Rs.)	EMD (Rs.)
8	3000002024	Ultrasonic Cautery	23	5,750	11,50,000

#### Read as:

SI. No.	Rfx No.	Item Description	Qty.	Tender Processing Fee (Rs.)	EMD (Rs.)
8	3000002024	Ultrasonic Cautery	45	5,750	22,50,000

# (2) Tender timeline:

## **Existing:**

SI. No.	Description	Schedule
d.	Closing date & time for submission of online bids	29.09.2017, 1800 hrs IST
c.	Closing date & time for submission of tender processing fee and EMD in physical form*	30.09.2017, 1400 hrs IST
e.	Time and date of opening of online bids	30.09.2017, 1430 hrs IST

#### Read as:

SI. No.	Description	Schedule
d.	Closing date & time for submission of online bids	12.10.2017, 1200 hrs IST
c.	Closing date & time for submission of tender processing fee and EMD in physical form*	12.10.2017, 1400 hrs IST
e.	Time and date of opening of online bids	12.10.2017, 1430 hrs IST

# Section VII Technical Specification

# Item sl. no. 8

# Ultrasonic cutting & coagulation device with advanced Radio frequency energy

Para	EXISTING	READ AS
	Ultrasonic cutting & coagulation device with advanced Radio frequency energy	Ultrasonic cutting & coagulation device, advanced Radio frequency/Bipolar energy and monopolar energy system
A.1	System should be a single/dual generator with single footswitch that provides ultrasonic energy and advanced RF energy technology for soft tissue dissection and vessel sealing	System should be a single/dual generator with single/dual footswitch that provides ultrasonic energy and advanced RF energy technology for soft tissue dissection and vessel sealing
A.6	Should be able to power ultrasonic energy instruments with <b>45 KHz and above frequency.</b>	Should be able to power ultrasonic energy instruments with 35 KHz and above frequency. The RF/bipolar & monopolar generator wattage should be mlnimum 130 Watts
A.8	Should be able to power energy instruments with microprocessor controlled bipolar electrosurgical radiofrequency technology with a quasisinusoidal forced impedance output.	Should be able to power energy instruments with microprocessor controlled bipolar electrosurgical radiofrequency technology with a <b>sinusoidal</b> forced impedance output.
A.10	Should be compatible with 360 shaft rotation and can simultaneously seal and transect vessel upto 7mm, large tissue pedicles and vascular bundles with system feedback	Should be compatible with <b>220 deg or more</b> shaft rotation and can simultaneously seal and transect vessel upto 7mm, large tissue pedicles and vascular bundles with system feedback
A.11	Should provide temperature controlled energy delivery which should maintain tissue temperature approximately at 100 deg C and hand instruments that provide tissue/vessel seal strength to withstand bursting pressure of 7 times the systolic pressure	Should provide temperature controlled energy delivery which should maintain tissue <b>temperature less than 100 deg C</b> and hand instruments that provide tissue/vessel seal strength to withstand bursting pressure of <b>minimum of 3 times</b> the systolic pressure
A.12	Should be compatible with ultrasonic energy instruments which can simultaneously seal and transect vessels upto 7mm, large pedicles and vascular bundles with ultrasonic energy only with system feedback	Should be compatible with integrated RF/bipolar and ultrasonic energy instruments which can simultaneously seal and transect vessels 7mm, large pedicles and vascular bundles with ultrasonic energy with system feedback
A.13	All hand probes for open and lap procedures should be able to simultaneously cut and coagulate tissues with integrated hand activation control buttons.	All hand probes (description given in BOQ) for open and lap procedures should be able to simultaneously cut and coagulate tissues with integrated hand activation control buttons.

Para	EXISTING	READ AS
A.15	Should confirm to the following international standards EN(IEC) 60601-1, EN(IEC) 60601-1-2, EN(IEC) 60601-2-2, EN (IEC) 60601-1-8 & system should be European CE & US FDA approved.	System should be <b>European CE with 4 digit notified body no. OR US FDA</b> approved.
A.18	Well-equipped service centre, should be ISO certified.	Well-equipped service centre should present in India with trained OEM Engineers/Technicians
C.2	Adapters for ultrasonic and rafiofrequency instruments	Adapters for ultrasonic and rafiofrequency instruments (if required)
C.4	RF energy 5mm lap hand activated probe capable of sealing blood vessels upto 7mm in diameter, 35cm with 3mm curved tip	Ultrasonic and RF/bipolar integrated energy 5mm lap hand activated probe capable of sealing blood vessels upto 7mm in diameter, 35cm with 3mm curved/straight tip
C.5	Ultrasonic 5mm lap hand activated curved coagulating shear with next generation adaptive tissue technology which gives regulated power delivery for improved thermal management and audible feedback tone for generator surgical efficiency, capable of sealing blood vessels upto 7mm in diameter using two hand activation buttons, proprietary non stick coated active blade to reduce tissue sticking, 36cm shaft length with ergonomic handle	Deleted
		Added para: Note- Bidder may offer either integrated or standalone monopolar device of any make which should be US FDA or European CE with 4 digit notified body no
		Added Para: BOQ
		Ultrasonic cutting & coagulation device, advanced Radio frequency/Bipolar energy and monopolar energy system - 1 no
		Dissecting Shears Straight Handpiece Open with transducer:  a. Dissecting Shears Straight Handpiece Open - 10 pcs.  b. Transducer Open for Dissecting Shears Straight - 01 reusable
		Dissecting Shears Curved/straight Handpiece Laparoscopic with transducer a. Dissecting Shears Curved Handpiece Laparoscopic - qty 10 pcs b. Transducer Open for Dissecting Shears curved - 01 reusable

Para	EXISTING	READ AS
		Vessel Welder /cutting and sealing Straight Handpiece Open with transducer
		a. Vessel Welder/ cutting and sealing Straight
		Handpiece Open - qty 10 nos
		b. Vessel Welder/ cutting and sealing Straight
		Transducer Open - 01 reusable
		Vessel Welder / cutting and sealing Straight/curved
		Handpiece Laproscopic with transducer
		a. Vessel Welder/ cutting and sealing
		curved/Straight Handpiece Open - qty 10 nos
		b. Vessel Welder/ cutting and sealing Straight
		Transducer Open - 01 reusable
		Accessories for Monopolar device
		(a) reusable (2Nos) and single use, split type (20
		Nos each) neutral electrode for adults along
		with cable for neutral electrode and fixation
		device wherever required,
		(b) reusable (2Nos) and single use, split type (20
		Nos each) neutral electrode for children along
		with cable for neutral electrode and fixation
		device wherever required,
		(c) sterilisable (2 Nos) and disposable (40 Nos)
		electrode handle with finger switch with cable
		for electrode handle,
		(d) Five sets of electrodes each (long and short)
		with electrode container with Holder.
		(e) tip cleaner- 50 no.s,
		(f) bipolar forceps one straight and one bayonet
		type with cable,
		(g) cable for connecting to standard mono polar
		and bipolar laparoscopic instruments -01 each

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