SPECIFICATIONS FOR SURGICAL ELECTROCAUTERY / DIATHERMY MACHINE/ ESU

A) Electro Surgical Unit should be microprocessor controlled, US-FDA and European Certificate marked in accordance with the medical devices directive (93/42/EEC) 04 digit notified & Electro Surgical Unit should comply with the requirement of the medical device directive of class I equipment and electromagnetic compatibility.

B) The system should have Monopolar Cut & Coagulation Modes with microcontroller-basedtechnology & should adjust the power to get the desired surgical effect on the tissue. All settings should be controlled by the machine and according to the tissue delivery.

C) Should have Power and Voltage automatic regulation feature to prevent tissue damage and charring. The output voltage should be regulated at various levels.

D) The System should have LCD/ LED Backlight adjustment for good visibility in the operating room, patient plate monitoring facility, audiovisual alarm, and deactivate output if contact between the patient and the patient plate is not proper to eliminate the risk of patient burns.

E) Should have the optional facility of connecting reusable contact quality Monitoring Return Electrode Pediatric / Adult with 100% washable footswitches for terminal cleaning & disinfection – Monopolar & Bipolar

F) The Electro Surgical Unit should be supplied along with essential accessories from the same original equipment manufacturer, an affidavit for the same has to be submitted by the bidder, or else the bid will be rejected.

1. Diathermy Pad / Patient plate –adult/pediatrics with patient plate cable if Reusable – 01 with a shelf life of minimum 50 applications and if disposable 50 pcs
2. Monopolar two pedal footswitch 100% Washable / Water resistant (for terminal disinfection) with a minimum shelf life of 1000 applications or 24 months from date of supply -1no.
3. Bipolar one pedal footswitch 100 % Washable / Water resistant (for terminal disinfection)- with minimum shelf-life of 1000 applications or 24 months from date of supply - 1no
4. Monopolar electrosurgical pencil with different electrodes either Reusable 01 Unit with reusable 05 electrodes of various shapes with shelf life of minimum 50 applications or Disposable – 50 Units

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5. Non-sticky Bipolar forceps Straight & bayonet each with bipolar cord for forceps either Reusable 01 Unit with a shelf life of minimum 50 applications or Disposable – 50 Units.
6. Reusable universal adaptor for attaching several Laparoscopic hand instruments with a shelf life of a minimum of 50 applications -1no.
7. Cart with castors with unconditional replacement if break within 05years from the date ofinstallation.

Conditions for tender:

1. All accessories should be from the same Original Equipment Manufacturer for the main unit.
2. Instruments must be ISO certified and a copy should be enclosed. (The ISO Certificate must be issued by any organization accredited by the Bureau of Indian Standard or accredited by the international accrediting forum "IAF" (Certificate to be attached).
3. Should be USA FDA and European CE be approved by 4 digits notified body.
4. Other necessary certifications if any required will be provided by the bidder for the smooth functioning of the machine.
5. Installation process should be performed by O.E.M trained service engineers/ service representatives on OEM letterhead or Service Report within 15 days of supply, with the mandatory provision of providing preventive services visit of OEM trained Service Engineer/ Service Representative quarterly per year till the completion of warranty period (i.e., 20 visits for the first 05 years) & further quarterly visits (04 visits/year) year till the completion of CMC period.
6. The equipment should have a Brand name/ Model Number embossed/etched on the equipment.
7. All the technical specifications in the compliance statement must be supported by Original Literature from the firm/ O.E.M with highlighting Numbering & flagging of all technical certificates.
8. Offered Equipment should have a strong Government Installation base.
9. Offered Equipment should have a Regional Sales Service Centre of the Original Equipment Manufacturer in the region for a 95 % uptime guarantee.
10. For the offered main unit, the essential, optional required consumables'/accessories' shelf life should be declared on the Original Equipment Manufacturer's letterhead.

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11. In case of technical snag/failure/breakdown the response time for the inspection should be within 24 hours and repair within 05 days otherwise provide a service machine/ alternate arrangement to be made till the period of recovery of the breakdown of the unit, failing which attracts penal action as per the decision of institute/ hospital.
12. For offered equipment the Training of technical staff and users should be performed by Original Equipment Manufacturer trained Service Engineers at the proper designated place- at bidders' cost.
13. Company should quote their latest model and need to provide an affidavit for the same.
14. As a tendering process the Demonstration of the offered Equipment is Mandatory at hospital/institute premises or other designated places at the bidder's cost.
15. The bidder must comply with the General Financial Rules and their modifications if any issued by the Government of India- 2017.
16. Any bidder from a country that shares a land border with India will be eligible to bid in the tender only if the bidder is registered with the Competent Authority (i.e., Registration certificate issued by the Ministry of Commerce and Industry (Department for Promotion of Industry and Internal Trade- DPIIT after October 2020). If any such bidder is not registered with DPIIT they will be liable for technical disqualification.
17. Principal (OEM) must authorize only one agent to be quoted in the bid otherwise multiple quotes through different agents in the same bid will be canceled.
18. The Bidder and its OEM both have to submit a notarized affidavit on the Indian Non-Judicial Stamp Paper of Rs.100/- that the bidder has not quoted the price higher than the current financial year and last financial year supplied to any government Institute/ Organization/ reputed Private Organization. OEM also has to submit that the price quoted by the bidder in the bid is on its behalf and the lowest in the current and last financial year in the country. Therefore, if at any stage it has been found that the supplier and its OEM have quoted lower rates than those quoted in this bid; the Institute (the purchaser) would be given the benefit of lower rates by the Supplier and any excess payment if any, will become immediately payable to the Institute (the purchaser). If such an affidavit is not submitted, the bid will be outrightly rejected. (Part of technical bid).
19. Guarantee / Warranty Period: Separate offers of Comprehensive Maintenance Contract (CMC on main equipment) and Annual Maintenance Contract (AMC on main equipment) for further 5 years after expiry of 5 years of warranty (i.e., 6^{th}, 7^{th}, 8^{th}, 9^{th} and 10^{th} years) in rupees only (and on basis of percentage of price) should be included in a financial bid in the absence of which the offer is liable to be rejected. Payment for CMC/AMC shall be made only after the

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expiry of the warranty of 5 years, in case the Institute (the purchaser) decides for availing of CMC/AMC services. Contract for CMC/AMC shall be decided on expiry of warranty but rates (not more than 5% inclusive of all taxes for 6^{th} to 10^{th} year) will be frozen at the price of an issued purchase order before the release of payment by the Institute (the purchaser). However, the Institute (the purchaser) may decide not to enter into any CMC/AMC contract without assigning any reason for the same, which shall be binding upon the bid.

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