Technical Specification for Pediatric Cysto-urethroscopy Set (01 Set)

GENERAL SPECIFICATIONS:

- 1. Should be a completely integrated system with components like telescopes, cysto-urethroscope sheath, obturators, resectoscopes, working instruments, and light source system should be from the same single manufacturer.
- 2. Telescopes should be of standard sizes, compatible with various light sources and camera heads.
- 3. Should be US FDA/ CE European/ Indian equivalent approved product.
- 4. Product should be lightweight with good quality metal, durable, with easy assembly and handling.
- 5. Product should have MDD/ BSI/ IEC, etc. safety standards where ever applicable, whether listed in this document or not.
- 6. Power input to be 220-240V AC, 50 HZ fitted with Indian plug.
- 7. All the documentation including but not limited to user manuals, service manuals etc. should be provided in English only.

TECHNICAL SPECIFICATIONS AND SCOPE OF SUPPLY:

1. Telescopes (01)-

- a. Straight telescope 0 degree.
- b. Diameter 1.9 mm, Working Length 17 20 cm.
- c. Autoclavable.
- d. Fibre optic light transmission incorporated.

2. Telescopes (01)-

- a. Straight telescope 25 30 degrees.
- b. Diameter 1.9 mm, Working Length 17 20 cm.
- c. Autoclavable.
- d. Fibre optic light transmission incorporated.

3. Cysto-urethroscope (01)-

- a. Cysto-urethroscope sheath with obturator 8/8.5 FR.
- b. With working channel allowing 3-4 FR instrument.
- c. Autoclavable.
- d. Should be supplied with the following instruments:
 - 3.d.1. Flexible biopsy forceps 3 Fr, Working Length 230 250 mm (02 in number).
 - 3.d.2. Flexible grasping forceps 3 Fr, Working length 230-250 mm (03 in number).

4. Resectoscope (01)-

- a. Resectoscope sheath 9 Fr.
- b. With obturator.
- c. With Luer Lock stop cock.
- d. Y connector
- e. Spring mechanism with a connecting tube for inflow.
- f. Movable thumb support and fixed irrigation port.

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- a. Electro tome consisting of:
 - 4.g.1. Working element passive cutting action and compatible with resectoscope sheath (01 in number).
 - 4.g.2. Cutting loop (05 in number).
 - 4.g.3. Coagulating electrode, hook-shaped, with ball end (01 in number).
 - 4.g.4. Coagulating electrode, angled, pointed (03 in number).
 - 4.g.5. Cold/ Sickle Knife, Hook shape (10 in number).
 - 4.g.6. Telescope bridge, with one lockable channel (01in number).
 - 4.g.7. Monopolar high-frequency cord, working length 300cm (04 in number).

5. Integral/ Composite Cystoscopes (01)-

- Paediatric Compact cysto-urethroscope, 8-9 Fr., a.
- Offset/ angled eyepiece with straight working channel. b.
- 12-degree telescope, Fiber optic light transmission incorporated.
- d. Two lateral irrigation ports.
- e. One 4 -5 Fr instrument working channel.
- Autoclavable. f.
- g. With the following instruments:
 - 5.g.1. Grasping forceps for foreign body removal, double-action jaw, Semi-flexible/ rigid 3 Fr to 5 fr Working length 260-300 mm (03 in number)

6. Fibre-optic Light Cables (02)-

- Should be lightweight have a diameter of about 2.5-3.5 mm with a length of 250 300 cm, heat-resistant.
- Should be flexible and autoclavable.

7. LED Light Source (01)-

- 220 V, Illumination equal to 175-200 watts or more.
- Simple user interface.
- Standby mode should be available.
- d. Universal jaw assembly to adapt to any make of fiber-optic cable.
- More than 20000 to 30000 hours bulb life.
- Color temperature should be between 4500 to 6500 K. f.
- To be supplied with all necessary accessories such as power cables etc.
- Certified to IEC and class 1 protection.
- 8. Suitable customizes trays for safe sterilized and storage of above instruments should be provided along with cleaning brushes and wires as required

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).

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- 3. Should be USA FDA and/ or 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. In warranty and CMC all accidental damages/ breakage/ leakage/ punctures/ manufacturing defects and wear and tear of all sorts will be covered apart from consumables like valves/ buttons/ batteries, filters, procedural endo therapy accessories etc.
- 7. The equipment should have a Brand name/ Model Number embossed/etched on the equipment.
- 8. 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.
- 9. Offered Equipment should have a strong Government Installation base.
- 10. Offered Equipment should have a Regional Sales Service Centre of the Original Equipment Manufacturer in the region for a 95 % uptime guarantee.
- 11. For the offered main unit, the essential, optional required consumables'/accessories' shelf life should be declared on the Original Equipment Manufacturer's letterhead.
- 12. 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.
- 13. 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.
- 14. Company should quote their latest model and need to provide an affidavit for the same.
- 15. 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.

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- 16. The bidder must comply with the General Financial Rules and their modifications if any issued by the Government of India- 2017.
- 17. 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.
- 18. 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.
- 19. 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).
- 20. 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., 6th, 7th, 8th, 9th and 10th 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 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 6th to 10th 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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