

अखिल भारतीय आयुर्विज्ञान संस्थान (एम्स), गुवाहाटी All India Institute of Medical Sciences, Guwahati

स्वास्थ्य और परिवार कल्याण मंत्रालय,भारत सरकार के तत्वावधान में एक वैधानिक निकाय (A statutory body under the aegis of Ministry of Health and Family Welfare, GoI)

Changsari, District- Kamrup, Assam, PIN-781101

Date: 13.08.2024

WEB CHALLENGE NOTICE

Ref. No. 4-216/2023-24/AIIMS/GHY/PROC-PULMONARY/1469

The notice is being uploaded on the web site <u>www.aiimsguwahati.ac.in</u>, <u>CPPP</u> & <u>https://tenderwizard.com</u>.

Sub: Verification and Justification of proprietary nature through 21 days Web- Challenge on the official website of AIIMS, Guwahati and CPPP before Procurement of "APC Cryotherapy Diathermy Unit" on proprietary basis against proprietary article certificate of the Original Equipment Manufacturer (O.E.M)- Inviting Comments thereon.

Department of Pulmonary Medicine, AIIMS, Guwahati is intending to buy an equipment namely "**APC Cryotherapy Diathermy Unit**", from M/s Erbe Elektromedizin GmbH, Waldhorenlestrasse 17, D-72072, Tubingen, Germany.

M/s Rounak Medicos Vindamandir Path, Bhetapra, Guwahati, Assam is the subsidiary and the Indian channel partner of the above said Original Equipment Manufacturer (O.E.M) of "<u>APC Cryotherapy Diathermy Unit</u>" (Namely, M/s Erbe Elektromedizin GmbH, Waldhorenlestrasse 17, D-72072, Tubingen, Germany).

The Original Equipment Manufacturer (OEM), M/s Erbe Elektromedizin GmbH, Waldhorenlestrasse 17, D-72072, Tubingen, Germany has declared in the Proprietary Certificate provided in their company's letter head that the sole manufacturer of the equipment namely <u>APC</u> Cryotherapy Diathermy Unit"

The notice is being uploaded for general information of prospective Manufacturer/Authorized Distributor/Dealer to submit their objection/comments, if any, on proprietorship of "<u>APC Cryotherapy Diathermy Unit"</u> Make: M/s Erbe Elektromedizin GmbH, Waldhorenlestrasse 17, D-72072, Tubingen, Germany, they may submit their proposal along with specifications, supported by all documentary evidence and a price quotation.

The objection/proposal/comments, if any should be sent in sealed cover to the office of Faculty Incharge, Procurement Cell, AIIMS, Guwahati, District- Kamrup (Assam), Pin-781101. Or through email to procurement@aiimsguwahati.ac.in so as to reach on or before dated on 03.09.2024 failing which it will be presumed that no other firm is interested to offer comments/ proposal/objection and case will be decided on its merits.

The Ref. No 4-216/2023-24/AIIMS/GHY/PROC-PULMONARY/1469, due on 03.09.2024 (before 5:00 PM) should be superscripted on sealed envelope.

Enclosures:

- 1. Proprietary Certificate of Manufacturer M/s Erbe Elektromedizin GmbH, Waldhorenlestrasse 17, D-72072, Tubingen, Germany.
- 2. Authorization provided by the OEM to M/s Rounak Medicos Vindamandir Path, Bhetapra, Guwahati, Assam .
- 3. Technical specification of the equipment namely "APC Cryotherapy Diathermy Unit".

Note from pre-page

Copy to:

Indenting Officer : For kind information please.
 PS to ED : For kind information please.
 IT Cell, AIIMS Guwahati : For kind information please.

Sd/-Administrative Officer AIIMS, Guwahati





Proprietary Certificate

To whom it may concern

ERBECRYO® 2

This is to certify that the ERBECRYO® 2 is a proprietary product, manufactured by Erbe Elektromedizin GmbH, Waldhoernlestrasse 17, 72072 Tuebingen, Germany. We are the only manufacturer of this product and this is not manufactured by any other company elsewhere in the world.

Comment of the Commen

Erbe Elektromedizin GmbH Waldhoernlestrasse 17

Date 2022-03-10

Natalie Zierhut, Business Manager Asia Pacific & Spain

हाँ किला जेख बस्त्रलारी
DR.NITA MEBS,MD,DM)
(MBBS,MD,DM)
सहायक प्राच्यापक / Assistant Professor
सहायक प्राच्यापक / Pulmonary Medicine
स्वरण विकाल विभाग / Pulmonary Guwahati

Proprietary Certificate





MANUFACTURER'S AUTHORIZATION

LOA 23-24/178

03.01.2024

All India Institute of Medical Sciences Department of Pulmonology Silbharal Changsari, Guwahati, Assam 781101

Sir,

Erbe Medical India Pvt. Ltd, is 100% subsidiary of **Erbe Elektromedizin GmbH Germany** who are established and reputable manufacturers of Electrosurgical Diathermy Units, Advanced Vessel Sealing, and other energy solutions viz. Argon Plasma, Waterjet, Smoke evacuation and Cryo products. We have our manufacturing at **Erbe Elektromedizin GmbH, Waldhorenlestrasse 17, D-72072, Tubingen, Germany**.

This letter is intended to authorize M/s Rounak Medicos Vindamandir Path, Bhetapra Guwahati, Assam to quote bid, negotiate and conclude the contract with you for Erbe Cryoworkstations manufactured by us.

No company or firm or individual other than **M/s Rounak Medicos** are authorized to bid, negotiate and conclude the contract in regard to this business for your institution

This authorization is valid till 31.03.2024 and will be renewed as per the fiscal year (if required)

Yours faithfully,

For Erbe Medical India Pvt Ltd

Yash Sharma

Tender and Distribution Coordinator

हरं किता नेच बस्नतारी
DR.NITA MECH BASUMATARY
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Revised specification

Advanced MOBILE THERAPEUTIC CRYO WORK STATION for Pulmonary Department

Intended use: For debulking and removal of central airway growths/tumors and relief of airway obstruction

Technical specifications:

- 1. Unit should comprise of Cryo system with flexible Cryo Probes from the same OEM to perform Biopsies, Recanalization & devitalization
- Integrated High End RF Electro Surgical Unit for electrosurgical Cut & Coagulation modes for optimum effect of HF surgery & dedicated high end Argon plasma coagulation unit for homeostasis of bleeding tissues & devitalization of pathological tissues with non-contact technology for coagulation (all from the same OEM)
- 3. The equipments should have brand name and Model Number embossed/etched on the equipment, must be supported by original literature of the OEM with mandatory regional & head office of the OEM principal company for providing after sales service with dedicated trained service engineers/service representatives team of O.E.M principal company
- 4. The equipment's Installation process & training should be performed by OEM trained service engineers/service representatives within 30 days of supply. Installation report should be submitted on OEM letterhead, with the mandatory provision of providing preventive services visit of OEM trained service engineers/service representatives quarterly per year till completion of warranty period (20 visits for the first 5 years) & further quarterly visits (04 visits/year) till completion of CMC period of 5 years (after end of warranty period)
- 5. The equipments should strictly comply uptime guarantee of 95%. In case of technical snag/failure/breakdown the response time for the inspection of trained O.E.M service engineer should be within 24 hours and repair within 05 days, for major breakdown & repair time of the unit is more than a week, the mandatory provision of keeping a service machine till the period of recovery of breakdown of the unit, failing which attracts penal action.
- 6. The complete equipments accessories & consumables should be of same Original Equipment

 Manufacturer & demonstration of the model mandatory at hospital premises at OEM cost.

De qual from

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Dr. Ritesh Agarwal Professor Deptt, of Pulmonary Medicine PGI, Chandigarh डॉ किट्टा केंग्र बस्त्रवारी DR.NITA MECH BASUMATARY DR.NITA MECH BASUMATARY (MBBS,MD,DM) स्कारक मध्यापक / Assistant Professor स्वाराज मध्यापक / Assistant Professor स्वाराज मध्यापक / Assistant Professor स्वाराज मध्यापक / Assistant Professor

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- 7. The Cryo System should be US-FDA & European Certificate marked in accordance with the medical devices directive (93/42/EEC), EN 60601 1 type CF & Class I Equipment and Electromagnetic Compatibility Certificate & ISO Certificate marked.
- 8. The Cryo System should be programmable based, monochrome display, activation via footswitch and the minimum freezing temperature should reach within 5 seconds mounted on imported original mobile cart with wire basket & CO₂ Cylinder (02 Units) compatible with cooling gas CO₂ gas as coolant & provided with connection pipe for gas exhaust.
- The Cryo System should be flow controlled for operating gas pressure between 45 65 bar & should have feature to count the reprocessing cycle of the instrument.
- 10. The System should have Effect Settings up to 5 depending on the type of instruments used, with a Programmable memory of up to 10 settings with activation from Foot Switch.
- 11. The System should work on Frequency of 50/60Hz with a line current of 0.4-0.8 Amp.
- 12. The System should have dimension not greater than 410x130x370mm & of weight less than 7kg.
- 13. The Cryo System should be supplied along with Disposable flexible Cryo Probe, for Different Procedures use (Total 15 Nos.)
- 14. The Mobile Cryo Workstation should be able to get synchronized with other compatible Energy Units of same make & OEM so that can be used an Advanced Cryo Workstation.
- 15. The Complete Mobile Pulmonary Therapeutic Cryo Work Station should be supplied with the Original Mobile Cart of the same Original equipment Manufacturer. (OEM) & CO2 Cylinder only.

RF Energy Platform High End Surgical-Electro Surgical Generator unit

- The electro surgical generator should be a 400watt touch screen display with 15 digital signal processors.
- Unit should facilitate monopolar and bipolar functions
- Unit should have a Step guide suggesting appropriate setting configurations for every instrument and application.
- The system should make 25 million measurements/sec for better tissue effect and should measure tissue impedance through power peak system.

System should have wifi compatibility for future OR integration.

Dr. Ritesh Aga Professor

Professor

Depth. of Pulmonary Medicine

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- Plug & play with 5 or more universal multi-functional sockets to accommodate any instrument.
- Remote function to allow the user to access 6 sub programs directly from the sterile field.
- Endo cut modes for snare resection of vascularized lesions and tracheal stenoses.
- · Facility for socket exchange
- Soft Coagulation mode with quick start function to be used with endoscopic coagulation forceps.
- Dry cut & Swift Coagulation mode for optimized dissection in advanced endoscopic Pulmonary cases.
- The generator should work on a supply voltage of 100-120 VAC & 220-240 VAC
- Power consumption at Max HF power should be 550 watts with max pulse power consumption of 1600 watts.
- · Soft coagulation bipolar mode to facilitate use of bipolar instruments.
- Supply frequency should be in the range of 50-60 Hz.
- Facility to store 1800 programs or applications.
- Facility to show the active instruments on the screen display.
- The generator should have an inbuilt feature of accessory assignment.
- The generator should be supplied with the latest Generation Argon plasma coagulation unit having forced APC, pulsed APC and precise APC modes from the same OEM.
- · Unit should support Nessy as a neutral electrode safety feature for the patient's benefits.

Argon Plasma Coagulation (APC Unit)

For management of bleeding and devitalisation of tissue abnormalities achieved by optimal coordination with RF generator

- The Argon Plasma Coagulation system should have automatic parameters setting for various types of instruments and automatic depth-controlled plasma regulation.
- · Should have three different APC modes suitable for different indications
 - Precise APC adjustment made using the effect settings for finest surface coagulation
 - Pulsed APC adjustment made using the parameter power settings for effective staunching of bleeding and tissue ablation
 - Forced APC adjustment made using the parameter power settings for angiodysplasia,

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Dr. Ritesh Agarwal

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tissue reduction

- Should have Adjustable argon flow rate from 0.1L/min to 8L/min in steps of 0.1L/min with automatic regulation of selected flow rate.
- Should have the facility to use unique hybrid instruments for conditions like Barrett's Esophagus
- Should have automatic monitoring of flow rate and Argon supply and auto purge facility. It should have the facility to connect with central gas supply.
- Should give visual display of argon gas bottle content and should give Acoustic alarm when bottle content reaches a minimum.
- Should have facility for activation of unit by foot pedal of the Electro Surgical unit.

Following accessories to be supplied from Same Single OEM for Surgical Procedures -

- Footswitch with facility for swapping between programs 2 Nos.
- Disposable Patient plate with equipotential ring 100 Nos.
- Filter integrated Argon Plasma Coagulation flexible probe (side fire) 10 Nos.
- Filter integrated Argon Plasma Coagulation flexible probe (axial fire) 10 Nos.
- Filter integrated Argon Plasma Coagulation flexible probe (circumferential fire) 10 Nos.
- · Straight APC probes 10 Nos.
- Monopolar cable for Endoscopic instruments 2 Nos.
- Argon Gas Cylinder for APC Unit with 3-5 Liters Capacity 02
- Cryo Single use probes 1.1mm 10pc, 1.7mm 10pc, 2.4mm 5pc
- It should be European CE / FDA certified.

हर्ष किता जेच बस्जाति DR.NITA MECH BASUMATARY DR.NITA MECH BASUMATARY (MBBS,MB,DM) शास्त्रक शास्त्रपक / Assistant Professor शास्त्रक शास्त्रपक / Assistant Professor शास्त्रक शास्त्रपक / AliMS Guwahati

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