

**ALL INDIA INSTITUTE OF MEDICAL SCIENCES
ANSARI NAGAR, NEW DELHI-29.
STORES SECTION (DO)**

Ref. No. 33/Stores(DO)/Pead/PAC/2018-19/FSC

Dated-05/02/2019

Sub:- Purchase of "Portal reverse osmosis (RO) water treatment unit for hemodialysis – 01 No" for the Department of Pediatrics at AIIMS, New Delhi-110029, on proprietary basis Inviting comments thereon.

The Institute is in the process to purchase **"Portal reverse osmosis (RO) water treatment unit for hemodialysis – 01 No** at AIIMS, New Delhi from **M/s. Fresenius Medical Care, Germany** through **M/s. Scientific Engineering Works, Delhi** The **PAC** Certifications by **M/s. Fresenius Medical Care, Germany** as well as the user department are attached.

The above documents are being uploaded for open information to submit objections, comments, if any, from any manufacturer regarding proprietary nature of the equipment/item within 15 day from the date of issue/uploading of the notification giving reference No. **33/Stores(DO)/Pead/PAC/2018-19/FSC**. The comments should be received in office of Stores Officer (FSC), Store Section (DO), Animal House Building, Near Biotechnology Building at AIIMS on or before **20/02/2019** upto **12.30 p.m.** failing which it will be presumed that any other vendor is having no comment to offer and case will be decided on merits.

Yours faithfully,


SR. STORES OFFICER (DO)

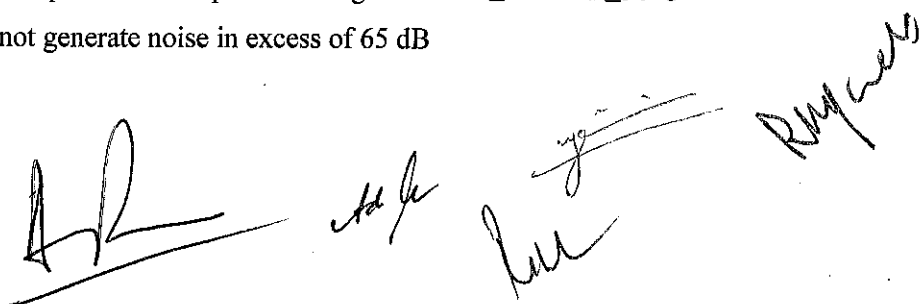
Encl: Related documents enclosed.

DEPARTMENT OF PEDIATRICS
ALL INDIA INSTITUTE OF MEDICAL SCIENCES

Equipment name	Portable Reverse Osmosis (RO) Water Treatment Unit for Hemodialysis	
Quantity	One	
Approx. cost		
Warranty/Guarantee	Five years comprehensive warranty	

TECHNICAL SPECIFICATIONS

1. Should provide water of quality that meets standards for dialysate listed by International Organization for Standardization (ISO-13959/23500) and American Academy of Medical Instrumentation (AAMI)
2. Should be able to produce 250 liters per hour of permeate at 1.5 bar, that can support hemodialysis on up to 5 hemodialysis machines at a time
3. Should be microprocessor based and classified as medical device Class II-b
4. Should display essential parameters such as permeate conductivity, temperature, feed water and permeate/concentrate flow and yield
5. Should have inbuilt capacity to calculate and display permeate supply (in liter/min) and temperature and raw water consumption (in liter/min) and pressure
6. Should have inbuilt dual column softener (alternate mode) with fully automatic brine, fill & clean cycles, and a brine tank incorporated in the system
7. Should have inbuilt charcoal filter of cartridge type
8. Should have inbuilt cartridge filters of 10 and 20 micron
9. Should have an inbuilt ultraviolet lamp before the reverse osmosis (RO) membrane
10. The yield setting should range from 55% to 75%
11. Should have an internal leakage sensor
12. Should have semi- automatic chemical disinfection and semi-automatic decalcification systems
13. Should have programmable, fully automated, rinse cycle for membrane wash
14. Should have a water saving system that adjusts the permeate output and yield to the number of machines being used
15. There should be provision of OFFLINE and ONLINE mode of permeate supply, that allow permeate supply to be used to run dialysis machines directly without collecting permeate in the tank
16. Should have compact design and be portable (easy to move on wheels)
17. Should have a stainless steel/powder coated chassis
18. Should be operable on single phase power supply of 220-240VAC and 50Hz
19. Should be operable at temperature range between $\leq 5^{\circ}\text{C}$ and $\geq 30^{\circ}\text{C}$
20. Should not generate noise in excess of 65 dB



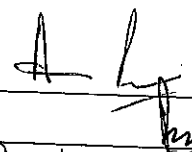
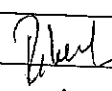
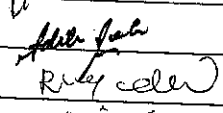
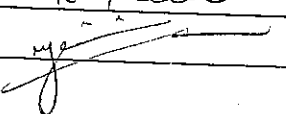
21. Should have 'AUTO START/STOP programming' facility
22. Should come with warranty in form of five years of comprehensive maintenance contract and additional five years of annual maintenance contract
23. The unit should also be supplied with requisite consumables/spare parts as specified below. Rates of all these consumable/reagents/spare parts (for use during next 5 years from installation) should be mentioned in the price bid, along with an undertaking in the technical bid. These consumables/reagents/spare parts should be compatible with the water treatment unit and have a shelf life of at least 1-year from the date of supply:
 - a. Charcoal 5 μ filter: Five every year; total 25 filters over 5 years
 - b. 10 μ soft filter: Five every year; total 25 filters over 5 years
 - c. Salt: 35 bags (25 kg each) per year; total 175 bags
 - d. Disinfectant cans (5 liters each): Five every year; total 25 cans over 5 years
 - e. RO membrane: Two in 5 years; replaced at 2.5 years and 5 years from installation
24. Company Responsibility:
 - Company should be in market for at least 5 years
 - The parent company has the sole responsibility of warranty and CMC even if the company's distributor is quoting to supply the machine.
 - Company personnel shall have the following responsibilities:
 - Elective visit once a week, day as decided by the department
 - Preventive machine maintenance four times in a year
 - Response time for acknowledgment of complaint: Within 30 minutes
 - Response time for physical presence within one working day
 - Machine uptime 355 days in a year
 - Machine downtime 48 hours, with a penalty of Rs. 5000/- every day after downtime
25. Documents to be enclosed:
 - Service manual in English
 - Product catalog and user manual in English
 - Compliance Report: To be submitted in a tabulated and pointwise manner, clearly mentioning the page number of original catalog of data sheet
 - Essential and additional equipment list: To be provided, including those required for providing calibration and routine preventive maintenance support, as per manufacturer documentation
 - Spare parts and accessories: List of important spare parts and accessories provided with the machine, part numbers and cost

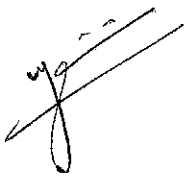
- Local components: A clearly defined list of components/parts of machine or its accessories that are to be provided by Indian counterpart/agent, that are not being provided with the machine. The costs of these components and their replacement frequency should be clearly stated
- Institution supply list: A complete list of the institutions where the machine has been supplied in last five years, along with the name, mobile and office contact details of the person handling the machine
- Details about company website where machine details and brochure are available
- Log book with instructions for regular maintenance and its checklist
- Job description: Clearly defined job description of the hospital staff and company service engineer
- User certificate and satisfactory performance report of the equipment in last five years from users in any central or state government hospital
- Letter of accreditation from the manufacturer of the machine stating that the machine to be supplied is new, the model is being manufactured as on tender date, the spare parts will be available for the next ten years from the date of delivery, and that service will be maintained even if the distributor changes
- Documentary evidence of local service facility with registered office in India: The service provider should have necessary equipment recommended by the manufacturer to carry out preventive maintenance service (PMS) as per guideline in the dialysis machine manual
- Should be accompanied by comprehensive warranty for 5 years and 5 additional years of comprehensive maintenance contract

Specifications finalized and approved on 31 July 2018.

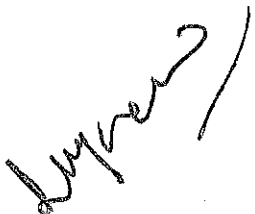
Members of Specifications Committee

1. Prof. Arvind Bagga, Department of Pediatrics
2. Prof. Pankaj Hari, Department of Pediatrics
3. Prof. Rakesh Lodha, Department of Pediatrics
4. Dr. Aditi Sinha, Department of Pediatrics
5. Dr. R. K. Yadav, Department of Nephrology
6. Dr. Kanika Jain, Department of Hospital Administration







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**ALL INDIA INSTITUTE OF MEDICAL SCIENCES
ANSARI NAGAR, NEW DELHI - 110029**

PROPRIETARY/SPECIFIC BRAND GOOD CERTIFICATE

1. Item/Type/Model no. required along with specification	Item: Portable, microprocessor based (feedback controls for water quality, disinfection, rinsing) Water Treatment Unit (WTU) for Hemodialysis (ONE only) Model No: Aqua WTU 250 LPH
2. Is the item a spare part/attachment or accessory for an existing equipment	Essential equipment (not spare part or attachment)
3. Name of the manufactures/supplier of the item proposed by the indenter	M/s Fresenius Medical Care AG & Co. KGaA
4. Are they sole manufacture/sole distributors of the item	Yes
5. Is there any other item with similar/equivalent specification available in the market to meet the job requirement envisaged. If the answer is yes, way the same can't be procured. Demanding officer should bring out comparative functional advantages/cost effectiveness of the recommended item from those offered by other	No
6. What were the efforts made to locate alternative source of supply or use other substitutes.	Highly pure water is required for Hemodialysis in children. For this, we need a portable, microprocessor based (feedback controls of water quality, disinfection, rinsing) closed - Water Treatment Unit which accommodates various components of water treatment required for hemodialysis in a small compact design. Procuring locally made components and assembling them is not a viable option. A portable unit is requested, which (i) can be flexibly moved around in the ward and intensive care units where it is used bedside; and (ii) occupies less space and can be accommodated within the available hemodialysis area. Microprocessor based unit significantly improves the water quality and controls disinfection and rinsing.
7. Why open/limited tender can't be resorted to for locating alternative source	This is a proprietary based item, only manufactured by M/S Fresenius Medical Care AG & Co. KGaA. It is unlikely that any other vendor will bid for the product if an open or limited tender is floated as no other company manufactures compact, microprocessor based water treatment unit.
8. Are the proprietary item certify that the rates are reasonable or not	Yes. The item is being provided at reasonable cost. A smaller size of this unit was procured by AIIMS Jodhpur from the same company recently, and the order copy is enclosed.
9. Any other justification for procuring item from single source.	As in 6 above

Signature of indenter
(Demanding officer)

17/9/18

(Counter signed)
(Head of the Department)

Dr. Ashok K. Deorari

Dr. Ashok K. Deorari, MD, FAMS
आचार्य एवं निदेशक/Professor & Head

पुष्पेश्वर चिकित्सा विभाग (Department of Pediatrics)
ए.आई.एम.एस. नई दिल्ली/A.I.I.M.S., New Delhi-110029

I certify that the item at sr. no. 1 above is required to be procured on single tender basis as the source of the supply is definitely known/ the specified brand proposed was advantage in meeting our functional requirements and limited tender system could be dispensed with as they would serve no useful purpose in this particular case.

(Strike out whichever is not applicable)

17/9/18

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**FRESENIUS
MEDICAL CARE**

INDIA

Proprietary Certificate

To whom it may concern:

We, **Fresenius Medical Care AG & Co. KGaA**, 61346 Bad Homburg, Germany hereby certify that below mentioned products are proprietary items of Fresenius Medical Care AG & Co. KGaA.

The below mentioned products are manufactured by and only for Fresenius Medical Care AG & Co. KGaA.

S. No.	Item	Article No.
1	Aqua WTU 250 LPH	6325701
2	Aqua WTU 125 LPH	6325691

M/s Fresenius Medical Care India Private Limited is an affiliated company and ultimately owned by Fresenius Medical Care AG & Co. KGaA.

Only M/s Fresenius Medical Care India Private Limited or any other authorized representative as appointed by M/s Fresenius Medical Care India Pvt Ltd. is authorized to bid, negotiate, sell and conclude the contract in regard to this business in India.

For and on behalf of Fresenius Medical Care AG & Co. KGaA

Jean DeSombre
Senior Vice President & General
Counsel for Asia Pacific Region

30 AUG 2018

Chris Chuang
Vice President
Quality & Regulatory Affairs Asia Pacific

30 AUG 2018