

ALL INDIA INSTITUTE OF MEDICAL SCIENCES

ANSARI NAGAR, NEW DELHI-29.

STORES SECTION (DO)

Ref. No. 36/Stores(DO)/Pead/PAC/2019-20/FSC

Dated-30/01/2020

Sub:- Purchase of "Portable Reverse Osmosis (RO) Water Treatment unit for Hemodialysis – 01 Unit." for the Department of Pediatric at AIIMS, New Delhi-110029, on proprietary basis Inviting comments thereon.

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The Institute is in the process to purchase "Portable Reverse Osmosis (RO) Water Treatment unit for Hemodialysis – 01 Unit. at AIIMS, New Delhi from M/s. Fresenius Medical Care AG & Co. KGaA, Germany through M/s. Scientific Engineering works, Delhi. The PAC Certifications by Fresenius Medical Care AG & Co. KGaA, 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. 36/Stores(DO)/Pead/PAC/2019-20/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 20/02/2020 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.

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

**Proprietary Article Certificate (PAC) (Machinery & Equipment)**

- (i) The indented goods are manufacture by **M/s Fresenius Medical Care AG & Co. KGaA**
- (ii) Item Name: **Portable Reverse Osmosis (RO) Water Treatment Unit for Hemodialysis**
- (iii) Model No: **Aqua WTU 125 LPH**
- (iv) Vital technical Performance Parameters required which makes the requirement proprietary<sup>##</sup>: **Technical specifications are attached. Please note that hemodialysis water has to meet stringent requirements that comply with international guidelines on hemodialysis water quality and quality of medical devices including use of microprocessor for safety reasons. These requirements are not are not met with by standard portable RO units that dispense potable (drinking) water for domestic or commercial use, and are made in India.**
- (v) No other make or model is acceptable for the following reason:  
**Please note reply to (iv), above. This portable, closed unit 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 as the portable unit (i) should be able to be flexibly moved around in the ward and intensive care units; (ii) occupy less space and can be accommodated within the available hemodialysis area; (iii) requirements of water for use in hemodialysis machines are stringent and not met by local R.O. water units that supply drinking water. The unit required must be microprocessor based with appropriate alarm to ensure patient safety.**

It is certified that market survey has been done and found that no other manufacturer is manufacturing similar/equivalent specifications which can fulfil the vital requirements of end user.






Signature of TSEC

With Name, Designation, Department and Hospital/Institute/DGHS

<sup>##</sup>Note: TSEC should clearly mention the vital functional parameters requirements which end user essentially require and are manufactured by only one manufacturer mentioned in Serial No (i)

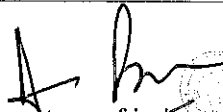

**डॉ. अशोक क. देवरासी**  
 Dr. Ashok K. Decrari, MD, FAMS  
 Professor & Head  
 Department of Pediatrics  
 अ.भ.म.स., नई दिल्ली / A.I.I.M.S., New Delhi-110029


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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	Aqua WTU 125 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, why the same can't be procured. Demanding officer should bring out comparative functional advantages/cost effectiveness of the recommended item form these offered by other	No Hemodialysis water has to meet stringent requirements that comply with international guidelines on hemodialysis water quality and quality of medical devices including use of microprocessor for safety reasons. These requirements are not met with by standard portable RO units that dispense potable (drinking) water for domestic or commercial use, and are made in India.
6. What were the efforts made to locate alternative source of supply or use other substitutes.	This is a portable, closed unit 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 as the portable unit requested, but not the locally procured and assembled components. (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.
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.
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): Dr. Renu Jaiswal/Department of Pediatrics  
अ.भा.आ.सं., नई दिल्ली/A.I.I.M.S., New Delhi-110029

 Dr. Ashok K. Deorari, MD, FAMS  
(Counter signed)  
(Head of the Department) Professor & Head  
आचार्य एवं विभागाध्यक्ष / Department of Pediatrics  
बालरोग विभागाध्यक्ष  
अ.भा.आ.सं., 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)

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**DEPARTMENT OF PEDIATRICS**  
**ALL INDIA INSTITUTE OF MEDICAL SCIENCES**

Item Name	Portable Reverse Osmosis (RO) Water Treatment Unit for Hemodialysis
Quantity	1 (One) unit
Cost	Rs. 22,00,000
Warranty/Guarantee: Comprehensive warranty for 5 years and five additional years of comprehensive maintenance contract	

**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 125 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

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*[Signature]*

*[Signature]*

*[Signature]*

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  $5\mu$  filter: Five every year; total 25 filters over 5 years
  - b.  $10\mu$  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
    - Testing of water quality delivered by unit, for chemical and microbiological quality, from standard laboratory, once every six months, free of cost
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

Specifications finalized and approved on 14 October 2019.

**Members of the specifications committee:**

1. Prof. Arvind Bagga, Department of Pediatrics:
2. Prof. Pankaj Hari, Department of Pediatrics:
3. Dr. Aditi Sinha, Department of Pediatrics:
4. Dr. R. K. Yadav, Department of Nephrology:
5. Dr. Jitender Sodhi, Department of Hospital Administration:

*(Signatures of Prof. Arvind Bagga, Prof. Pankaj Hari, Dr. Aditi Sinha, Dr. R. K. Yadav, and Dr. Jitender Sodhi)*

*(Signature of Dr. Ashok K. Deorari)*



डॉ. अशोक कु. देवरासी  
Dr. Ashok K. Deorari, MD, FAMS  
आचार्य एवं विभागाध्यक्ष / Professor & Head  
बालरोग चिकित्सा विभाग / Department of Pediatrics  
आ.भा.आ.सं., नई दिल्ली / A.I.I.M.S., New Delhi-110029



**FRESENIUS  
MEDICAL CARE**

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**SECTION – XIII  
MANUFACTURER'S AUTHORISATION FORM**

**Dated : 09.12.2019**

- The 'Director'
- All India Institute of Medical Sciences
- Ansari Nagar, New Delhi-110029, India.

Dear Sir,

We, Fresenius Medical Care India Pvt Ltd, who are 100% subsidiary of Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg Germany who are proven and reputable manufacturers of Portable Reverse Osmosis Plant, Model Aqua Wtu 125 LPH having factories at Germany, hereby authorize Messrs, Scientific Engineering Works, having office at B-116, Swasthya Vihar, Delhi -110092 (name and address of the distributor) to submit a bid, process the same further and enter into a contract with you against your requirement as contained in the above referred TE documents for the above goods manufactured by us.

We also state that we are not participating directly in this bid for the following reason(s):  
*Our authorized distributor is responsible for supply of Goods to this assigned Delhi/NCR Territory.*

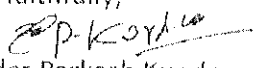
We further confirm that no supplier or firm or individual other than Messrs. Scientific Engineering Works, (name and address of the above distributor) is authorized to submit a bid, process the same further and enter into a contract with you against your requirement as contained in the above referred TE documents for the above goods manufactured by us.

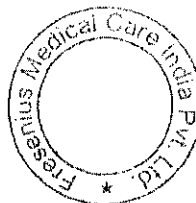
We also hereby extend our full warranty, CAMC as applicable as per clause 15 of the General Conditions of Contract, read with modification, if any, in the Special Conditions of Contract for the goods and services offered for supply by the above firm against this TE document.

We also hereby confirm that we would be responsible for the satisfactory execution of contract placed on the authorized distributor and the spares for the equipment shall be available for at least 10 years from the date of supply of equipment.

We also confirm that the price quoted by our distributor shall not exceed the price which we would have quoted directly.

Yours faithfully,

  
Chander Parkash Kundra  
Sr. Manager - PPP  
Fresenius Medical Care India Pvt. Ltd.  
SAS Tower-B, 14th Floor, Sector - 38  
122001 Gurgaon M: +91 7838005321  
chander.kundra@fmc-asia.com



**Fresenius Medical Care India Private Limited**

CIN - U24231DL2006FTC147436

Regd. Office : S-21, Second Floor, Star City, District Centre, Mayur Place, Mayur Vihar Phase-1, New Delhi-110091 Web: [www.freseniusmedicalcare.asia](http://www.freseniusmedicalcare.asia)

**Corporate Office Gurugram**  
14th Floor, SAS Tower-B,  
The Medicity, Sec-38,  
Gurugram-122 001  
Tel : 0124 - 6642 500  
Fax : 0124 - 6642 506

**Branch Office Mumbai :**  
B-307, Everest Grande,  
Mahakali Caves Road,  
Andheri (East), Mumbai - 400 093  
Tel : 022 - 4217 6500  
Fax : 022 - 4217 6501

**Branch Office Kolkata :**  
4th Floor, Akash Tower,  
781, Anandpur,  
EM bypass, Kolkata - 700 107  
Tel : 033 - 3090 9500  
Fax : 033 - 3090 9506

**Branch Office Chennai :**  
2nd Floor (VTB Center), Old No. - 4,  
New No. -7, South Boag Road,  
T. Nagar, Chennai - 600 017  
Tel : 044 - 4396 0900  
Fax : 044 - 4396 0915



**INDIA**

**Proprietary Certificate**

**To whom it may concern:**

We, **Fresenius Medical Care AG & Co. KGaA, 61346, Bad Homburg, Germany** hereby certify that the below mentioned reverse osmosis system for haemodialysis is the proprietary item of Fresenius Medical Care AG & Co. KGaA.

S.N.	Item	Article No.
1	AquaWTU 125	6325691

**Fresenius Medical Care India Pvt Ltd.** is an affiliated company and ultimately owned by Fresenius Medical Care AG & Co. KGaA.

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

Bad Homburg, 13.09.2019  
Place and date



**FRESENIUS  
MEDICAL CARE**  
Fresenius Medical Care AG & Co. KGaA  
61346 Bad Homburg - Germany

*[Signature]*

**I. A. Dorothea Hoffmann**  
Associate Medical Device Regulatory

Fresenius Medical Care AG & Co. KGaA  
61346 Bad Homburg - Germany

*[Signature]*

**I. V. Annette Manck**  
Senior Expert Medical Device Regulatory Affairs

Fresenius Medical Care AG & Co. KGaA  
61346 Bad Homburg - Germany

*[Signature]*

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