



All India Institute of Medical Sciences Jodhpur

Admn//Prop/16/2016-AIIMS.JDH

Dated: - 08th March, 2017

Subject: Purchase of Hemodialysis with Portable RO (5008 S Online Plus with Aqua WTU 125 for the department of Nephrology at AIIMS, Jodhpur on proprietary basis - **Inviting comments thereon.**

The Institute is in the purchase of Hemodialysis with Portable RO (5008 S Online Plus with Aqua WTU 125 for the department of Nephrology at AIIMS, Jodhpur from M/s Fresenius Medical Care AG & Co. KGaA, 61346, Bad Homburg, Germany on proprietary basis. The proposal submitted by M/s Messrs Scientific Engineering Works, B-116, Swasthya Vihar, Delhi and PAC certification by user are attached.

The above document are being uploaded for open information to submit subjection, comments, if any from any manufacturer regarding proprietary nature of the equipment within 21days of issue giving reference Admn/Prop/16/2016-AIIMS.JDH. The comments should be received by office of Administrative Officer, Medical College at AIIMS, Jodhpur on or before 29th March 2017 upto 03:00 PM failing which it will be presumed that any other vendor is having no comment to offer and case will be decided on merits.

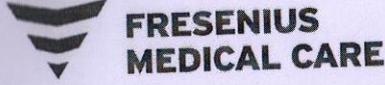
Yours faithfully,

Administrative Officer

Enclosed: Related documents enclosed.



All India Institute of Medical Sciences Jodhpur



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 dialysis machine is the proprietary item of Fresenius Medical Care AG & Co. KGaA.

No.	Item	Article No.
1	5008S Basic ONLINEplus	M201211

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.



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

Bad Homburg, 15.09.2016
Place and date

i. A. Dorothea Hoffmann
Associate Medical Device Regulatory

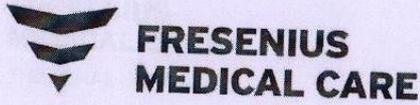
Fresenius Medical Care AG & Co. KGaA
61346 Bad Homburg - Germany

i. V. Annette Manck
Senior Expert Medical Device Regulatory Affairs

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

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Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg, Germany, T +49 6172 609-0. Registered Office and Commercial Register: Hof an der Saale, HRB 4019, VAT-ID No.: DE 811127677, Chairman of Supervisory Board: Dr. Gerd Krick
General Partner: Fresenius Medical Care Management AG, Registered Office and Commercial Register: Hof an der Saale, HRB 3894
Management Board: Rice Powell (Chairman), Michael Brosnan, Ronald Kuerbitz, Dr. Olaf Schermeier, Kent Wanzek, Dominik Wehner,
Harry de Wit, Chairman of Supervisory Board: Stephan Sturri
Bank Account: Commerzbank AG, Frankfurt/Main, IBAN: DE23 5008 0000 0711 6731 00, SWIFT/BIC: DRESDEFF501



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 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, 06.02.2017
Place and date



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

i. A. Dorothea Hoffmann
Associate Medical Device Regulatory

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



All India Institute of Medical Sciences Jodhpur



**FRESENIUS
MEDICAL CARE**
THE RENAL COMPANY

Annexure-III MANUFACTURER'S / PRINCIPAL'S AUTHORIZATION FORM

Dated 8th Feb 2017

To,
Director,
All India Institute of Medical Sciences,
Jodhpur

Sir,

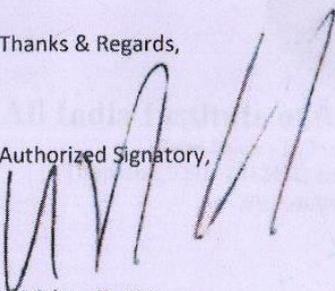
We, Fresenius Medical Care India Pvt. Ltd, 100% subsidiary of Fresenius Medical Care, Germany who are established and reputable manufacturers of 5008 HEMODIALYSIS MACHINE & Portable RO Aqua WTU 125 L having factories at Bad Homburg, Germany hereby authorize Messrs Scientific Engineering Works, having office at B- 116, Swasthya Vihar, Delhi – 110092. To quote, negotiate the above goods manufactured by us.

No company or firm or individual other than Messrs Scientific Engineering Works, having office at B- 116, Swasthya Vihar, Delhi – 110092. are authorized to quote, negotiate and conclude the contract in regard to this business.

We hereby extend our full guarantee and warranty as per the conditions of tender for the goods offered for supply against this tender by the above firm.

Thanks & Regards,

Authorized Signatory,


V. Vishnu Kumar
National Sales Manager
For and on behalf of Messrs
Fresenius Medical Care (India) Pvt. Ltd,
M: +91 9176917200
Email ID: Vishnu.Kumar@fmc-asia.com

Fresenius Medical Care India Private Limited

CIN: U24231DL2006FTC147436

Regd. Office : S-21, Second Floor, Star City, District Centre, Mayur Palace, Mayur Vihar Phase-1, New Delhi-110091 Web: www.freseniusmedicalcare.asia

Corporate Office Gurgaon :
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Tel. : 0124 - 6642600
Fax : 0124 - 6642606

Branch Office Mumbai :
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Mahakali Caves Road,
Andheri (East), Mumbai - 400 093
Tel. : 022 - 4217 6500
Telefax : 022 - 4217 6501

Branch Office Kolkata :
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781, Anandpur,
EM bypass, Kolkata - 700107
Tel. : 033 - 3090 9500
Telefax : 033 - 3090 9506

Branch Office Chennai :
No. 6 & 7, 3rd Floor, Kasi Arcade,
116, Sri Thyagaraya Road,
Tiruyarantya Nagar, Chennai - 600 017
Tel. : 044 - 4396 0900
Fax : 044 - 4396 0915



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S. No	Item	Technical Specification	Qty
01.	Haemodialysis Machine with Portable RO Machine	<ol style="list-style-type: none">Should be microprocessor controlled & capable of providing therapies such as Conventional HD, Online HDF, HF & features such as Online priming, Acetate & Bicarb dialysis, Volumetric UF, Sodium/UF profiling, Online help options (in case of alarm), BPM, OCMHigh resolution TFT touch screen with functional keys & provide cumulative graphical display of treatment data & physiological trends including sodium & UF profiles.Should display different menus indicating blood system, preparation, dialysate, UF, Treatment, Reinfusion, Cleaning, System parameters & screen saver option.Safety Features: Should be a close system design with volumetric dilution of concentrates with RO water & Volumetric UF. Self-Test after switching ON, Start-up T1 test before each treatment, to ensure functioning of all hardware components.Blood Circuit:<ol style="list-style-type: none">Vascular Access: Single Needle click clack should be available. Blood pump with features such as flow range of 20-600ml/min, with 10ml increments adaptable to standard A-V blood lines. An emergency hand crank should be provided to enable reinfusion in case of power failure.Heparin Pump: Should be automatic or manual start/stop, with infusion rate of 0.5- 10ml/hr in 0.1ml/hr increments. Heparinization stop time should be user-adjustable in 1min increment, & positive/negative extracorporeal blood circuit pressure should not affect infusion rate. Auto Bolus administration should be programmable from 1- 20ml/hr.Pressure Monitoring & Alarms: Venous pressure monitoring & adjustment in case of alarm condition. (Range: -100 to +500mmHg), Arterial pressure monitoring & adjustment in case of alarm condition. (Range: -300 to +300mmHg)Air Detection: Ultrasonic design & should be activated for air & micro bubbles over entire blood flow range. Sensitivity of detection mechanism should be specified in terms of air bubble size & on detection of excessive air, venous clamp should activate & blood pump stop.Reference point for level detector measurement should be about 13 ± 4mm, from upper edge of venous chamber.Dialysis Circuit:<ol style="list-style-type: none">Treatment/Therapies: Should facilitate Acetate & Bicarbonate dialysis. Variable sodium & bicarbonate options. Volumetric UF & Sodium/UF profile options.Dialysate Flow Rates: A Range of 100-1000ml/min should be available, with resolution of 100ml/min, with Accuracy- $\pm 10\%$Temperature Control & Alarm: Control Range: 34.0 to 39.0 deg Celsius With 0.5 increments. Alarm Limits: 33.5 to 40.0 deg CelsiusConductivity Control & Alarm: Range: 12 to 16mS/cm.	03

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	<p>Accuracy: ± 0.1 mS/cm</p> <p>e) Blood Leak Detection: Photo detector used, & alarm should be activated for blood loss</p> <p>f) Volumetric UF: Control Range: 0-4L/hr, given by set values of UF volume & treatment time, with accuracy $\pm 1\%$. TMP monitoring: -100 to +400 mmHg. Isolated ultrafiltration process should be provided.</p> <p>g) Equipment should be capable of on-line preparation of bicarbonate dialysis fluid & It should be handle by one hands only</p> <p>h) Ultra-pure Dialysate Filter: Should have hygienic connection for ultra-pure dialysate filter. Should have endotoxin retention capacity not less than 106 IU. Machine should have an automatic program to change filter, including emptying & filling cycles. Filter should have life span not less than 12weeks or 100 treatments. Filter should be arranged in cross flow setting & equipment should perform flushing during treatment automatically every 1hr. Filter change reminder should be available.</p> <p>7. Online Fluid Circuit: For HDF: Both option of Pre-dilution & post-dilution of blood should be available. Automatic control substitution program with pre/post dilution identity integrate function, dialyser integrate function, Effective blood flow rate integrate. HCT integrate function, Total protein integrates & UF rate integrate functions. Equipment should have 2 ultra-pure filters to prepare the online substitution fluid. Should be capable of online preparation of substitution fluid for priming & rinsing of extracorporeal ckt for HD/HDF/HF/ or as injection-bolus & reinfusion at the end of treatment. Substitution fluid delivery rate: 25 to 600ml/min in 1ml/min increment, with accuracy ± 0.1ms/cm & exchange volume -210L (max.)</p> <p>8. Dialysis Parameter Display: Equipment should display following parameters: Arterial Pressure, Venous Pressure, Blood flow rate, Dialysate Conductivity, TMP, UF volume, UF rate, Remaining treatment time, Heparin infusion rate, Alarm information, etc.</p> <p>9. Kt/V: Equipment should have: Inbuilt measurement & monitoring of effective Urea clearance K, Dialysis dose Kt/v, & Plasma sodium during dialysis This measurement should be done without any additional cost & disposable during each treatment Measuring accuracy: Clearance $\pm 6\%$ Kt/V $\pm 9\%$ Kt/V conductivity evaluation should be 12 bit with 2 channels & 2 CD cells (1 cell for basic machine function) & Measuring range: 12.8 – 15.7 mS/cm, Accuracy: 0.05 mS/cm Kt/V temperature evaluation should be 12 bit with 2 channels & 2 NTC (1 NTC for basic machine function) & Measuring range: 33.5 – 41 °C, Accuracy: 0.2 °C</p>	
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10. Blood Pressure Monitoring: Equipment should have built in non-invasive device for measuring the patient blood pressure automatically. Cuff pressure range: 10-325 mmHg or wider choice; Systolic range: 30-280 mmHg or wider choice. MAP range: 20-255 mmHg or wider choice; Diastolic range: 10-240 mmHg or wider choice; Pulse rate range: 20-245 1/min or wider choice. Alarm values should be: Systolic range: 90 & 165 mmHg; MAP range: 70 & 120 mmHg; Diastolic range: 50 & 100 mmHg; Pulse range: 40 & 150 1/min.

11. Battery Backup: The equipment should be able to operate and monitor the extracorporeal circuit without interruption for 20-30 min. in case of AC power failure by backup battery.

12. Disinfection and Cleaning: Both chemical and heat disinfections should be performed. Sodium hypochlorite should be used as cleansing disinfectant. Various Programmable Cleansing Cycles should be provided with different phases and timings in accordance with different disinfectants. Should be One-touch fully automatic operation including pre-rinse, chemical-intake for combined disinfection & decalcification, post-chemical Mandatory rinse, and automatic power-off; without the need of any end-user handling during this whole disinfection process.

13. The machine should be US FDA/European CE approved

Accessories:

The machine should be supplied with:

Dialyzer (polysulfone membrane)

- 1) High Flux – 20 Pcs.
- 2) Low Flux – 80 Pcs.
- 3) Tubings: 100 pcs.
- 4) Online Bicarbonate bags: 100 pcs 900 gm
- 5) Hot disinfectant compatible with Machine: 3 PCs.

Specification of Online Water Treatment Unit (WTU).

- 1) Should be of compact design on wheels for easy movement.
- 2) Should be able to produce 125 vs 200 Liter/Hour of permeate.
- 3) The system must be Microprocessor based.
- 4) In build capabilities to show on display for Permeate (Supply in liter/min, Temperature) & for Raw Water (Consumption in Liters/min & Pressure)
- 6) Should have built in dual column softener with fully automated brine, fill and clean cycles, also have a brine tank incorporated in the system.
- 7) Should have built in cartridge type Charcoal Filter.
- 8) Should have fully automatic disinfection system in place.
- 9) Should have built in cartridge filter of 10 Micron and 5 Micron.
- 10) Should have programmable fully automated Rinse cycle for membranes wash.
- 11) There should be a provision of OFF line mode and ONLINE mode of Permeate Supply, in case permeate supply is to be used to run dialysis machines directly without collecting permeate to tank it should be possible.
- 12) There should be a water saving system in place which adjusts the

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	<p>output to the number of machines in use and control yield accordingly.</p> <ol style="list-style-type: none">13) Should not have noise level more than 65 dB14) Should deliver the water quality as per AAMI standard.15) Yield setting should be between 50 to 70 %.16) Should have EC certification attached with tender document.17) Provision of U-V filter at the final treated water supply point. <p>Note: Vendor should check quality of feed water in AIIMS, Jodhpur to ensure proper output before quoting the product.</p>	
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