

GOVERNMENT MEDICAL COLLEGE & HOSPITAL, SECTOR-32 CHANDIGARH

Department of General Medicine

Notice for procurement of Haemodialysis machine with SLED and HDF Model: 5008S being proprietary Article through GeM.

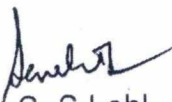
The Department of General Medicine of this institute intends to purchase Haemodialysis machine with SLED and HDF Model: 5008S through GeM having detailed specifications attached Annexure 'A':-

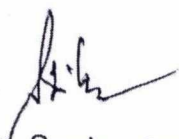
**Detailed Specifications:-**

As per Annexure 'A'.

As per knowledge of General Medicine department, the above said article/ equipment is only manufactured by M/s Fresenius Medical Care AG & Co. KGaA, 61346, Bad Homburg, Germany and the said firms sells the same through its affiliated company M/s Fresenius Medical Care India Pvt. Ltd. or any other authorized representative as appointed by M/s Fresenius Medical Care India Pvt. Ltd. in the Chandigarh/India region. The Proprietary certificate issued by the OEM is Attached as Annexure-B.

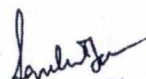
In case, there is any other OEM for the above said article, then they are requested to submit their proposal to the Director Principal, GMCH, Chandigarh through email dpgmch-chd@gmch.gov.in / hard copy latest by 08.10.2020, failing which it will be presumed that there is no other firm who manufacture the required article/ equipment and purchase will be processed and finalized from the available source.

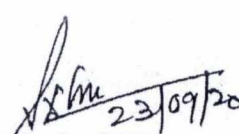
  
Dr. S. S Lehl  
Professor & Head

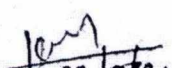
  
Dr. Sanjay D'Cruz  
Professor

## SPECIFICATION FOR HEMODIALYSIS MACHINE (SLED)

1. Machine should be of latest technology, upgradable to future software development with USB and Ethernet connectivity
2. Should have facility for conventional hemodialysis, slow extended dialysis and hemodiafiltration.
3. Should be easily transportable and mounted on sturdy lockable caster wheels.
4. Machine should have bacterial filters.
5. Single needle dialysis facility
6. Should have colour panel display 15inch
7. Automatic battery back-up for at least 15 minutes to run machine.
8. Dialysate temperatures selectable between 35 degrees C to 39 degree C.
9. Variable conductivity setting between 13 to 15 mS/cm.
10. Should have variable dialysate flow 100-800 ml/min.
11. Should have variable blood flow 50-600 ml/min.
12. Substitution fluid delivery rate should be 30-600 ml/min
13. Should have TMP monitoring: -100 to +400 mmHg.
14. Should have options of pre-dilution & post-dilution of blood should be available.
15. Should have cumulative graphical display of treatment parameters
16. Heparin infusion pump with automatic/manual start stop 0-5ml/hour
17. Inbuilt measurement and monitoring of effective urea clearance
18. Ultrasonic sensor for air & micro bubble detection.
19. Should have detector for blood leak detection & alarm.
20. Should have integrated heat (80° C) and chemical disinfection facility.
21. Should have volumetric UF (0-4L/hr) UF volume (0-9.99L/hr) & Sodium/UF profile options.
22. Should have facility for using bicarbonate cartridge capable of on-line preparation of bicarbonate dialysis fluid
23. Emergency hand crank provision in case of power failure
24. Should be capable of online preparation of substitution fluid for priming & rinsing of extra-corporeal circuit for HD/HDF/HF.
25. Audio visual alarms on limit violation of conductivity, blood leak, air leak, venous and arterial pressure, trans-membrane pressure alarms, dialysis temperature alarm, reverse UF, end of disinfection alarm, bypass alarm and blood pump stop alarm.
26. Should have automatic self test facility.
27. Should have auto ON/OFF facility.
28. Machine can be connected to computer to feed all data and trouble shoot any problem.
29. Ability to monitor pulse rate and NIBP with graphic and tabulated trends.
30. Power input to be 220-240 V AC, 50 Hz fitted with Indian plug.
31. Should be US-FDA/EU-CE/BIS approved
32. Manufacturer / Supplier should have ISO 13485 certification for quality standards.
33. Shall comply with IEC 60601-2-16 SAFETY requirements of medical electric equipment part 2 – particular requirements for the safety of Haemodialysis equipment.
34. Comprehensive warranty for 5 years supported.
35. CAMC (parts and service) after 5 years warranty if possible under GEM.
36. Comprehensive training for laboratory staff and support service till familiarity with the system.
37. Should have a Chandigarh service facility. The service provider should have the necessary equipments recommended by the manufacturer to carry out preventive maintenance test as per guidelines provided in the service / maintenance manual within 24 hours of being informed.
38. User / Technical/Maintenance manuals to be supplied in English.
39. Certificate of calibration and inspection.
40. List of Equipments available for providing calibration and routine Preventive Maintenance support. As per manufacturer documentation in service/ technical manual.

  
Dr. Safabmeet Singh Lehl

  
Dr. Sanjay D'Cruz

  
Dr. Kamal Singh

I N D I A

**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.

S.N.	Item	Article No.
<b>1</b>	5008S Version 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.

Bad Homburg, 06.02.2017  
Place and date



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

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Associate Medical Device Regulatory

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