Rajasthan Medical Services Corporation Limited, Jaipur

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No. F-8( ) RMSC/EPM/M-3/23-24/NIB-775/546 Dated: 26/9/23

CLARIFICATION/CORRIGENDUM/ADDENDUM

Sub:- Revised Technical Specifications and bid submission date of the rate contract for High Flow Nasal Cannula System (HFNC) for under NIB No. F-8() RMSC/EPM/M-3/NIB-775/2023-24/228 dated 12-7-2023

In Reference to subject cited above and NIB-775, the various representations received from the firms and issues raised by the Bidders are examined by the competent Authorities and technical committee. The following Clarification/Corrigendum/Addendum is issued for inclusion in Bid document & Technical Specification of items as below:-

Revised Technical Specifications of High Flow Nasal Cannula System (HFNC)

1. It should be complaint for use on patients in ICU, wards, Emergency department oxygen therapy .
2. It should be single system for treating Infant and pediatric patients.
3. **Device should have integrated flow generator to deliver flows from 2 to 50 liters/min or more.**
4. Inbuilt or Integrated Air/ Oxygen blending and Fio2 monitoring with facility to deliver wide range of oxygen concentrations from 21 to 100%.
5. **It should have Integrated or Inbuilt Compressor /turbine/piton as Air source.**
6. **Device should have capability to use oxygen from central gas pipeline as well as an oxygen concentrator or cylinder.**
7. **Noise level of device should be <35db at mid pressure range.**
8. Oxygen sensor should not require in field calibration.
9. **Alarm Indications for power failure, tube disconnection, tube blockages and low battery.**
10. Device should have thermal disinfection mode to minimize contamination, (If required in Quoted model).
11. Heated tube for sterilization of device should be provided, (If required in Quoted model).
12. Device should be capable to be installed on Mounting Tray and Pole with Castor & IV Hook. **Atleast two castors should be fitted with breaks.**
13. Complete HFNC Device or Core Parts (blender, humidifier), should be USFDA/European CE Certified (With four digit notified body number). (Certificate should be attach in Technical Bid).

    Or

    Complete HFNC device should have IEC 60601-1 & IEC 60601-1-2 (from NABL Lab/Govt. approved laboratories WIZ-STQC/ITDL or from any international certifying agency under notified body. (Certificate should be attached in Technical Bid).
14. **If humidifier is being provided as separate unit then it should be USFDA/European CE Certified (With four digit notified body number) or IEC IEC 60601-1 & IEC 60601-1-2 (from NABL Lab/Govt. approved laboratories WIZ-STQC/ITDL or from any international certifying agency under notified body.**

15. **Manufacturer of Complete HFNC device or core components (blender, humidifier), should be ISO- 13485 certified from IAF accredited Certification Body (Certificate should be attach in Technical Bid).**
16. **Compressor /Air source manufacturer (if required as separate unit in quoted model) should be ISO- 13485 certified from IAF accredited Certification Body (Certificate should be attach in Technical Bid).**

Note: Name of Item, Manufacturer, make, model , Item Produced by etc. , details shall be mentioned clearly on all relevant certificates/Testing reports or other related documents submitted in Technical Bid .

17. **Device should have battery backup to maintain uninterrupted air flow for at least 60 minutes.**
18. **Device should have Oxygen Inlet Tube and Air Filter. (If required)**
19. Device should be supplied with Patient Breathing Circuits/Tube – 2 pcs (Each) for Infant and pediatric patients.
20. The device should have temperature sensing mechanism to sense the temperature of delivered gases through consumable circuit.
21. The consumable circuit should have heating wire to accurately deliver warm and humidified gases and should have humidifier chamber for water.
22. Device should be supplied Nasal Cannula interface for proper fitting : 02 Pcs – Each for Infant and pediatric patients.
23. Device should have two years of warranty.
24. Device should have universal connection compatibility for certified HFNC Circuit / tubes/ other consumable kit.

Revised Bid Schedule:-

E-bids are invited as per following revised time schedule:-

Existing Dates				Extended Dates			
Last Date for Sale of Bid Form	Last Date of Receipt of Bid Form	Last Date of submission of bid document fees	Date of Opening of Technical Bid	Last Date for Sale of Bid Form	Last Date of Receipt of Bid Form	Last Date of submission of bid document fees	Date of Opening of Technical Bid
1.	2.	3.	4.	5.	6.	7.	8.
26.09.2023 11:00 a.m.	26.09.2023 6:00 p.m.	27.09.2023 03:00 p.m.	27.09.2023 03:00 p.m.	03.10.2023 11:00 a.m.	03.10.2023 6:00 p.m.	04.10.2023 03:00 p.m.	04.10.2023 03:00 p.m.

Note:- Please note that all above amendments/corrigendum in technical specifications/bid conditions is the integral part of and the bid document. This corrigendum/ addendum should be signed and annexed with bid document. All other terms & conditions remains the same.

Executive Director (E&M)
RMSCL, Jaipur