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No. F-8() RMSC/EPM/M-3/21-22/NIB-661/ 1756

Dated: 22/03/2022

CLARIFICATION/CORRIGENDUM/ADDENDUM

Sub:- Revised Amended Technical Specifications of the rate contract for High Flow Nasal Cannula System (HFNC) for under NIB No. F-8() RMSC/EPM/M-3/NIB-661/2021-22/1571 dated 07.1.22

In Reference to subject cited above and NIB-661, 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 the 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 paediatric patients.
- 3. Device should have integrated flow generator to deliver flows from 2 to 60 litres.
- 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 /Air source.
- 6. Oxygen sensor should not require in field calibration
- 7. Visual and audible alarm indication for Tube disconnects leaks, tube blockages and Water out and Hardware Fault with Error Codes. Audible power failure alarm.
- 8. Device should have thermal disinfection mode to minimize contamination, (If required in Quoted model).
- 9. Heated tube for sterilization of device should be provided, (If required in Quoted model).
- 10. Device should be capable to be installed on Mounting Tray and Pole with Castor & IV Hook.
- 11. Complete Device or core components like blender, humidifier should be USFDA/European CE Certified (With four digit notified body number) / IEC 60601. Compressor /Air source manufacturer should be ISO-13485 certified.
- 12. Device should have Oxygen Inlet Tube and Air Filter.
- 13. Device should be supplied with Patient Breathing Circuits/Tube 2 pcs (Each) for Infant and paediatric patients.
- 14. The circuit should have integrated temperature sensor with no need of external probes, cables or Adapter.
- 15. The Circuit should be supplied with a humidifier chamber for water.
- 16. The Circuit should have heating fine wire inside the circuit to gently and accurately deliver warm and humidified gases.
- 17. Device should be supplied Nasal Cannula interface for proper fitting: 02 Pcs Each for Infant and paediatric patients.
- 18. Device should have two years of warranty from manufacturer.
- 19. Device should have universal connection compatibility for certified HFNC Circuit / tubes/ other consumable kit.

Note:- Please note that all above amendments/corrigendum in technical specifications/bid conditions is the integral part of (Section-V, Schedule of Supply, and Point no. 3) and the bid document. This corrigendum/ addendum should be signed and annexed with bid document. All other terms & conditions remains the same.

Executive Director (EPM)
RMSCL, Jaipur