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No. F-8( ) RMSC/EPM/M-3/22-23/NIB-734/ 1124 Dated: 10/3/23

CLARIFICATION/CORRIGENDUM/ADDENDUM

Sub:- Revised Technical Specifications for the rate contract of High Flow Nasal Cannula System (HFNC) for under NIB No. F-8() RMSC/EPM/M-3/NIB-734/2022-23/985 dated 15-2-2023

In Reference to subject cited above and NIB-734, 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 paediatric patients.
3. **Device should have integrated flow generator to deliver flows from 2 to 60 liters 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 /Air source.
6. Oxygen sensor should not require in field calibration.
7. **Visual and audible alarm indication for tube disconnection leaks, tube blockages and hardware fault with error codes along with 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 HFNC Device or Core Parts (blender, humidifier), should be USFDA/European CE Certified (With four digit notified body number).
12. 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).
13. IEC 60601-1 Report of complete HFNC device issued from Accreditated NABL Laboratory or equivalent foreign Laboratory Internationally Accreditated for Testing Respiratory Medical Devices under Scope of Accreditation should be submitted in Technical Bid.
14. Compressor /Air source manufacturer (if required 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 .

15. Device should have Oxygen Inlet Tube and Air Filter.
16. Device should be supplied with Patient Breathing Circuits/Tube – 2 pcs (Each) for Infant and pediatric patients.
17. The device should have temperature sensing mechanism to sense the temperature of delivered gases through consumable circuit.

18. The consumable circuit should have heating wire to accurately deliver warm and humidified gases and should have humidifier chamber for water.

19. Device should be supplied Nasal Cannula interface for proper fitting : 02 Pcs – Each for Infant and paediatric patients .

20. Device should have two years of warranty from manufacturer.

21. 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 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