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Ref. No.:- F.02(124)/RMSCL/Proc./S&S(MD)/NIB-08/2022/ 748 Dated: 23/09/2022

Corrigendum-III

Subject: - Date extension, amendment in bid conditions and technical specifications in NIB-08/2022

Ref.:- F.02 (124)/RMSCL/Proc./S&S(MD)/NIB-08/2022/651 Dated: 29.08.2022

(Technical bid opening due on dated –30.09.2022)

The following amendments are made in bid conditions and technical specifications of NIB-08/2022

S. No	Item code	Existing Date / Conditions / specifications	Item code	Amended Date / Conditions / specifications
1.		Last date and time of submission of online bids: **29.09.2022 up to 06:00 PM** EMD, Tender fees, RISL fees through challan and Physically: **29.09.2022 up to 06:00 PM** Date and time of opening of Online technical bids: **30.09.2022 at 11:00 AM**		Last date and time of submission of online bids: **10.10.2022 up to 6:00 PM** EMD, Tender fees, RISL fees through challan and Physically: **10.10.2022 up to 06:00 PM** Date and time of opening of Online technical bids: **11.10.2022 up to 2:00 PM**
2.	NES9	**Annexure – VIII** **Annexure - XVIII** **Technical Specification for double blood bag with SAGM (350ml) general specification annexure-XVI and specification in annexure-XVIII** **Anti coagulant and preservative solution:** 1. CPDA/CPDA-1:The quantity of anti coagulant/pre(49ml/63ml.) 2. Clear and colorless 3. No dis coloration on storage at room temperature. 4. Manufacturer to supply anti coagulant quality check certificate.	NES9	**Annexure – VIII** **Annexure - XVIII** **Technical Specification for double blood bag with SAGM (350ml) / Triple blood bag with SAGM - 2 (350ml) general specification annexure-XVI and specification in annexure-XVIII** **Anti coagulant and preservative solution:** 1. **CPD/CPDA-1:The quantity of anti coagulant/pre(49ml/63ml.)** 2. Clear and colorless 3. No dis coloration on storage at room temperature. 4. Manufacturer to supply anti coagulant quality check certificate.

	NES10	Annexure – VIII Annexure - XIX **Technical Specification for double blood bag with SAGM (450ml) general specification annexure-XVI and specification in annexure-XIX** Capacity: • Double blood Primary bag-350ml One satellite bag (300ml) **Anti coagulant and preservative solution:** 1. CPDA/CPDA-1:The quantity of anti coagulant/pre(49ml/63ml.) 2. Clear and colorless 3. No dis coloration on storage at room temperature. 4. Manufacturer to supply anti coagulant quality check certificate.	NES10	Annexure – VIII Annexure - XIX **Technical Specification for double blood bag with SAGM (450ml) / Triple blood bag with SAGM - 2 (450ml) general specification annexure-XVI and specification in annexure-XIX** **Capacity:** • **Double blood** **Primary bag-450ml** One satellite bag (300ml) **Anti coagulant and preservative solution:** 1. **CPD/CPDA-1:The quantity of anti coagulant/pre(49ml/63ml.)** 2. Clear and colorless 3. No dis coloration on storage at room temperature. 4. Manufacturer to supply anti coagulant quality check certificate.
	NES13	Annexure – VIII Annexure - XXII **Technical Specification of Quadruple blood bag with SAGM (350ml) general specification annexure-XVI and specification in annexure-XXII** **Anticoagulant and preservative solution:** 1. CPD: (49 ml for 350 ml/ 63 ml for 350 ml.) in primary bag 2. SAGIVI (78 ml for 350 ml/100 ml for 450 ml) in first satellite bag 3. Clear & colorless 4. No discoloration on storage at room temperature 5. Manufacturer to supply anticoagulant quality check certificate	NES13	Annexure – VIII Annexure - XXII **Technical Specification of Quadruple blood bag with SAGM (350ml) general specification annexure-XVI and specification in annexure-XXII** **Anticoagulant and preservative solution:** 1. CPD: (49 ml for 350 ml/ 63 ml for 350 ml.) in primary bag 2. **SAGM (78 ml for 350 ml/100 ml for 450 ml) in first satellite bag** 3. Clear & colorless 4. No discoloration on storage at room temperature 5. Manufacturer to supply anticoagulant quality check certificate

	NES14	Annexure – VIII Annexure - XXIII **Technical Specification of Quadruple blood bag with SAGM (450ml) general specification annexure-XVI and specification in annexure-XXIII** **Anticoagulant and preservative solution:** 1. CPD: (49 ml for 350 ml/ 63 ml for 350 ml.) in primary bag 2. SAGIVI (78 ml for 350 ml/100 ml for 450 ml) in first satellite bag 3. Clear & colorless 4. No discoloration on storage at room temperature 5. Manufacturer to supply anticoagulant quality check certificate	NES14	Annexure – VIII Annexure - XXIII **Technical Specification of Quadruple blood bag with SAGM (450ml) general specification annexure-XVI and specification in annexure-XXIII** **Anticoagulant and preservative solution:** 1. CPD: (49 ml for 350 ml/ 63 ml for 350 ml.) in primary bag 2. **SAGM (78 ml for 350 ml/100 ml for 450 ml) in first satellite bag** 3. Clear & colorless 4. No discoloration on storage at room temperature 5. Manufacturer to supply anticoagulant quality check certificate
	NE32A	**Annexure – VIII** Specifications of Bed side Leucodepletion Filters for Blood Transfusion:-(For one unit of red cell) 1. Filters should be able to leuco-deplete red cells form leukocyte contamination separately for 1 unit of red cells and for 2 units of red cells each. 2. Filters should be having the capacity of log 4 reduction (99.99%) 3. Filters should not carry any charges it should be neutrally charged. 4. Filters material should be polyester woven / non- woven. 5. Leukocytes should be consistently averaging less than 0.5x105 residual leucocytes for one unit of red cell and 0.2*106 for two units of red cell. RBC recovery should be averaging more than 90%. 6. Filters should have hard / soft housing for optical monitoring. 7. Filtration loss should not be more than 35 ml for one unit red cell. 8. Should have integrated ≥ 40 µm, micro aggregate filter. 9. Should be US FDA/ European CE Certified.	NE32A	**Annexure – VIII** Specifications of Bed side Leucodepletion Filters for Blood Transfusion:-(For one unit of red cell) **1. Filters should be able to leuco-deplete red cells form leukocyte contamination separately for 1 unit of red cells.** 2. Filters should be having the capacity of log 4 reduction (99.99%) 3. Filters should not carry any charges it should be neutrally charged. 4. Filters material should be polyester woven / non-woven. **5. Leukocytes should be consistently averaging less than $0.5x10^5$ residual leucocytes for one unit of red cell. RBC recovery should be averaging more than 90%.** 6. Filters should have hard / soft housing for optical monitoring. 7. Filtration loss should not be more than 35 ml for one unit red cell. 8. Should have integrated ≥ 40 µm, micro aggregate filter. 9. Should be US FDA/ European CE Certified. **10. Filter should have air vent, to achieve transfusion with minimum loss.** **11. Packing Unit – Filter should have individual packing with bulk box pack. Quantity should be in multiple of 05 units or 40 filters per box**

	NE32B	**Annexure – VIII** Specifications of Bed side Leucodepletion Filters for Blood Transfusion:-(For two unit of red cell) 1. Filters should be able to leuco-deplete red cells form leukocyte contamination separately for 1 unit of red cells and for 2 units of red cells each. 2. Filters should be having the capacity of log 4 reduction (99.99%) 3. Filters should not carry any charges it should be neutrally charged. 4. Filters material should be polyester woven / non- woven. 5. Leukocytes should be consistently averaging less than 0.5x105 residual leucocytes for one unit of red cell and 0.2*106 for two units of red cell. RBC recovery should be averaging more than 90%. 6. Filters should have hard / soft housing for optical monitoring. 7. Filtration loss should not be more than 35 ml for one unit red cell. 8. Should have integrated ≥ 40 µm, micro aggregate filter. 9. Should be US FDA/ European CE Certified.	NE32B	**Annexure – VIII** Specifications of Bed side Leucodepletion Filters for Blood Transfusion:-(For two unit of red cell) **1. Filters should be able to leuco-deplete red cells form leukocyte contamination separately for 2 units of red cells each.** 2. Filters should be having the capacity of log 4 reduction (99.99%) 3. Filters should not carry any charges it should be neutrally charged. 4. Filters material should be polyester woven / non-woven. **5. Leukocytes should be consistently averaging less than $0.2*10^6$ for two units of red cell. RBC recovery should be averaging more than 90%.** 6. Filters should have hard / soft housing for optical monitoring. 7. Filtration loss should not be more than 35 ml for one unit red cell. 8. Should have integrated ≥ 40 µm, micro aggregate filter. 9. Should be US FDA/ European CE Certified.
	NES7	**Annexure – VIII** Dockable red cell filter 1. The predeposit storage leucodepletion filter for the leucodepletion of whole blood packed cells. 2. Filtration of whole blood and red cells must be completed for >90% of bags within 45 minutes from time at which flow of blood into the filter is opened. 3. The filter should be able to reduce the final count of leucocyte in the product to <5×10^6 per bag. 4. The filtration process should not reduce red cell to less than 85% of the initial red cell mass percentage of haemolysis<1%. 5. Usable with blood of core temperature in the range 4°C-30°C. 6. Filter material should be highly porous polyurethane/polyester material to ensure quality of red cell during filtration. 7. Filter should have a Pre filter 200micro meter to ensure two step filtration of blood 8. Filter housing: Material should be polycarbonated with housing volume of max 40ml. 9. Bag should be sterilized by Beta irradiation.	NES7	**Annexure – VIII** Dockable red cell filter **1. The predeposit storage leucodepletion filter for the leucodepletion of packed red blood cells.** 2. Filtration of whole blood and red cells must be completed for >90% of bags within 45 minutes from time at which flow of blood into the filter is opened. 3. The filter should be able to reduce the final count of leucocyte in the product to <5×10^6 per bag. 4. The filtration process should not reduce red cell to less than 85% of the initial red cell mass percentage of haemolysis<1%. **5. Usable for RBC blood of core temperature in the range 20°C-24°C.** 6. Filter material should be highly porous polyurethane/polyester material to ensure quality of red cell during filtration. **7. Filter should have a Pre filter 200micro meter to ensure two step filtration of blood. (Optional)** **8. Filter housing: Material should be polycarbonated / PVC soft housing with housing volume of max 40ml.** **9. Bag should be sterilized by Beta irradiation or ETO or gamma sterilization**

		10. The device should have drip chamber with by pass and one way valve to remove air inside the bag. 11. Transfer bag should be attached and have minimum 300ml capacity. 12. Each Dockable filter should be in a separate casing to maintain integrity and shape of the filters. 13. Market standing of more than 4 years. 14. Should have expiry of more than 18 months at the time of supply. Product labels should barcoded as per ISBT128. Secondary packing and shipping cartoons should be barcoded as per GSI-28.		**10. The device should have drip chamber with by pass or integrated air vent to remove air inside the bag.** 11. Transfer bag should be attached and have minimum 300ml capacity. 12. Each Dockable filter should be in a separate casing to maintain integrity and shape of the filters. 13. **Market standing of more than 4 years.** 14. Should have expiry of more than 18 months at the time of supply. Product labels should barcoded as per ISBT128. Secondary packing and shipping cartoons should be barcoded as per GSI-28.

Note:-

- **It may be noted that if any further amendments are issued then a corrigendum will be published and informed.**
- **Rest of the terms and conditions will remain the same.**

Executive Director (Proc.)
RMSCL