Ethiopian Pharmaceutical Supply Service

Ref.No: EPSS/06/624/02

Date: 26 MAR 2025

To: **All Participants of tender with Ref. No. ICB/EPSS6/SDG&RDF/MD/19/24**

Subject: **Amendment, Clarification and Bid Closing /Opening Date Extension**

Dear Sir/Madam;

We highly appreciate your interest to participate on the tender captioned above and reference is made to your kind request.

We hereby amend, clarify and newly added items as per the attachment and please consider the amendment, clarification and added items during your bid document preparation. Additionally Bid closing and opening date is extended to April 14, 2025 G.C 2:00 pm & 2:30 pm respectively. All the remaining terms, conditions and requirements are same as per the document and the bid price and security validity period shall consider the extended closing/opening date.

We apologize for any inconvenience you may face due to this amendment!

With Best Regards

Tibebu Hailu Mogessie
Pharmaceuticals & Medical
Supplies Procurement Tender
Management Directorate
P/Director

ENC: 8 Pages

CC:

- Medical Device Tender Management Team
- Archive

EPSS

Head Office
Address: Addis Ababa, Ethiopia
011-2763268 Director General
011-2763276 Public Relation Directorate
Hotline 8772 | P.O.Box. 21904
info@epss.gov.et | www.epss.gov.et

Section 3. Evaluation Methodology and Criteria

Certificate Priority:

1. **First Priority:** Valid Product specific Certificate from EFDA (for Quoted Model) & Valid Product specific Certificate from SRA Region (or WHO Certificate for Refrigerator);

2. **Second Priority:** Valid Product specific Certificate from SRA Region (or WHO Certificate for Refrigerator).

Note: For bidders or suppliers offering second-priority products, a Product Registration Commitment Letter must be submitted during the bid opening, and a product application letter from EFDA must be submitted during the bid evaluation period. Failure to submit the Product Registration Commitment Letter at the bid opening or the application letter from EFDA during the bid evaluation period will result in the bidder being considered non-compliant with the second priority.

N.B: A Technical evaluation will conducted for the bidder/supplier offered second priority product if the bidder/supplier offer first priority product fails to meet technical requirements

The following table shows list of regulatory schemes under Stringent Regulatory Authority (SRA) regions

S.No.	Stringent Regulatory Authority (SRA)	Remark
1	US Food and Drug Administration, USA	Valid 510K Notification Letter OR
		Valid Premarket Approval Certificate (PMA) OR
		Valid Certificate for Foreign Government OR
		Valid Free Sale Certificate
2	Ministry of Health, Labor and Welfare, Japan or PMDA (Pharmaceuticals and Medical Device Agency)	Valid Free Sale Certificate OR
		Market Authorization Certificate
3	Therapeutic Goods Administration (TGA), Australia	Valid Free sale Certificate OR
		Market Authorization Certificate
4	Health Science Authority, Singapore	Valid Free sale Certificate OR
		Market Authorization Certificate
5	Competent Authorities from one of the 27 Member States of the European Union who are responsible in Europe for the Regulatory oversight of Medical Device Please Refer link: https://european-union.europa.eu/easy-read_en	EU Technical documentation assessment certificate (Annex IX, Chapter II) MDR OR
		Market Authorization Certificate OR
		EC Full quality assurance certificate OR
		EC Product Assurance Certificate AND EC Type examination Certificate OR
		EC Full Product Quality Assurance Certificate for (MDD & IVDD), Extension from issuing notified body OR
		Valid Free sale Certificate
6	Medicine and Healthcare Products Regulatory Agency, UK	Valid Free sale Certificate OR
		Market Authorization Certificate
7	Health Canada, Canada	Valid Free sale Certificate OR
		Medical device License
8	Ministry of Food and Drug Safety, South Korea	Valid Free sale Certificate OR
		Market Authorization Certificate

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S.No.	Stringent Regulatory Authority (SRA)	Remark
Market Authorization or Free Sale Certificate from SRA Region For **Laundry Machine**		
1	USA	
2	Japan	
3	Australia	
4	Singapore	
5	27 Member States of the European Union	Please Refer link: https://european-union.europa.eu/easy-read_en
6	UK	
7	Canada	
8	South Korea	

- *Bidders or Suppliers offering second-priority products, must be submitted a product certificate from **EFDA** before contract signing period.*

*NB: For bidders or suppliers offering second-priority products, a Product Registration **Commitment Letter** must be submitted during the bid opening, and a product **application letter from EFDA** must be submitted during the bid evaluation period. Failure to submit the Product Registration Commitment Letter at the bid opening or the application letter from EFDA during the bid evaluation period will result in the bidder being considered non-compliant with the second priority.*

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S.N	Item Description	Unit	Qty	Bidder Offer	Status of Compliance	Payment Method
1	**1. Generic Name:** Automated Blood component centrifuge with consumable and supply	Set	7			90% of purchase order value upon submission of complete shipping document and The remaining 10% after receiving installation,user and technical training and commissioning confirmation letter from health facility
	2. Manufacturer:					
	3. Country of origin:					
	4. Model:					
	5. Clinical Purpose/Description:					
	Used for the preparation of blood components from Whole blood donation units					
	6. Technical Specification:					
	The machine shall produce blood componenets a minimum of (red blood cells ,leucoreduced plasma and platelets) in a single centrifugation step (Single run)					
	The machine shall be able to process a minimum of four units/bags of whole blood (450 ml WB) at a time					
	The system should be able to estimate the platelet yield index for the platelets units processed					
	system shall have optional feature to produce leuckoreduced plasma					
	the system shall have an easy to use system interface for operation and control by the laboratory personnel					
	The system shall have a data management/ software that is able to generate critical information related to its operation.The system must have feature to interface with the exiting blood bank information system at the blood bank					
	7. System Configuration Accessories, Spares, Consumables and other componenets:					
	All consumables required for installation and standardization of system to be given free of cost.					
	The Supplier must supply details of manufacturer's Quality Control data for batches.					
	Introductory kits for training and equipment validation will be given free of charge. Any quality Non conformity on kits the company must replace upon the quantities free of charge					
	The supplier must provide information on the consumables and supplies associated with the testing systems such as MSDS for all products , Package inserts for all products,COA of each lot , Stability data					
	The supplier should provide all complete accessories as per the machine requirement					
	As a minimum each reagent must be labeled with the following information:- Name of assay, the name of the reagent, the product code, the lot number, the expiry date & should have bar-coded identification of reagents.					
	Blood bag collecting 450ml (cassette) (shelf life ≥2 year)----59,664	set	59,664			
	8. Operating Environment;					
	Ambient tem temperature: 15°C to 28°C					
	Relative humidity: 30% to 80%					
	9. Utility Requirements:					
	Input voltage supply is single phase 220-240 VAC, 50HZ					
	10. Standards Certificates & Safety Requirements:					
	Should have FDA or CE certification					
	Should meet electrical safety specification as per IEC class I, It, types BF &CF					

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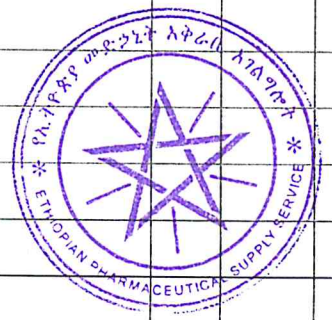
	Should meet general requirement for basic safety & essential performance of the medical electrical equipment as per IEC 60601-1-1 I :20 I 0 ,Specifically; [EC 60601-2-16 & IEC 60601-2-39					
	11. Installation/Training/Commissioning:					
	The supplier must be install, commissioning and maintain the machines by free of charges .					
	Training should be provided for testing and Quality professionals free of charge and the details of training offered should be specified.					
	The supplier must give consecutive technical training for Blood Bank Service staffs as applicable					
	12. Warranty/ Aftersales service:					
	Installation and user and technical training are mandatory and after sales service of the product must be provided with free of charges.					
	The supplier must be provide minimum of three years warranty including labour and spare part from the date of commissioning.					
	The Supplier should clearly set out a full maintenance and servicing schedule with no costs during warranty period					
	Suppliers must identify in advance a schedule of planned preventative maintenance (PPM) and provide this to the Laboratory Manager at the EBTBS Testing site. This must include a list of the dates for each visit and what will be done at each visit within a week of installation.					
	The Supplier must notify the testing site at least one month in advance of forthcoming routine maintenance visits. The Supplier must remain within the stated schedule.					
	Suppliers must notify the EBTBS at least 3 months in advance of the date of introducing any planned changes to the kit components or instructions for use.					
	Any essential software upgrades must be made available within the maintenance provision at no additional cost.					
	The Supplier's representative must liaise with laboratory management before commencing work to ensure that proposed activities have met the Authority's change control requirements and present the minimum disruption and hazard to both parties.					
	All work involving the use of a modem or other electronic data link must be approved in writing by an authorized EBTBS officer before proceeding.					
	The Supplier must provide full records of service/PPM, calibration and equipment upgrades. These must include:Logs of all work carried out during on-site visits or during a modem/data link to the equipment, listings of all equipment/spares used and of changes/upgrades made (including those made by modem/data link) and, an itemized PPM/Service Check-list.					
	Records must be completed, signed and dated by the Supplier's representative during the visit and a copy handed to the EBTBS authorized officer.					
	The Supplier must carry out documented installation qualification of any new items of equipment installed and/or changes made to existing equipment.					
	After PPM or equipment repair the Supplier must verify that all affected equipment is fully operational before departing the premises.					
	The EBTBS management must be notified of any equipment that is not operational or requires further remedial action, calibration or validation post service/repair.					
	Suppliers must provide written advice of hygiene standards required within the environment the instrumentation is being installed.					
	All records will remain the property of the blood bank					
	If an "in house" calibration of the instrumentation is required, the Supplier must provide written instructions including full methodology, associated equipment and documentation, required frequency and expected outcome.					



	Response times to notification of breakdown must be within 24 hour.					
	Repair of faults or validated backup instrumentation must be provided within 48 hours of notification					
	13 . Documentation:					
	should submit operational and technical Manual in English					
	Certificate of calibration and inspection from factory.					
	14 . Packaging and Labelling;					
	Packing of all the goods must be clearly marked and securely packed. Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.					
	Additional packing and labeling requirements should bear in each package					
	Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Service (EPSS)					
	Tender and Purchase Order No.					
	UMDNS Name and Model of the product					
	PO Box 25-11-276-32-65					
	Tel: +251-11-276-32-65					
	Fax: +251-11-275-25-55					
	Addis Ababa					
2	**1. Generic Name: Refrigerated Centrifuge**	Set	15			90% of purchase order value upon submission of complete shipping document and The remaining 10% after receiving installation,user and technical training and commissioning confirmation letter from health facility
	2. GMDN/UMDN Name:					
	3. Clinical Purpose/Description:					
	General purpose automatic refrigerated centrifuge used for blood component preparation.					
	4. Technical specification					
	General purpose automatic refrigerated centrifuge for blood component preparation,					
	Direct drive motor type, Programmable, microprocessor controlled, 115 programs plus manual mode, Multi stage programs,					
	Floor standing for large capacity, With a capacity of 16 blood bags minimum, Allowable density at least 1200kg/m3, easily moveable,					
	Maximum RPM/RCF 5000/7000Radius programmable for RCF and Integral calculation,					
	Dimension (HxWxD): aprrox. 38X32X40 in					
	Maximum noise 62dB					
	Temperature: +4°C to +22°C					
	9 acceleration profiles, 9 deceleration profiles					
	Timer 10 to 999 minutes, With safety lid lock					
	5. System Configuration Accessories, Spares, Consumables and other components:					
	All consumables required for installation and standardization of system to be given free of cost.					
	The Supplier must supply details of manufacturer's Quality Control data.					
	The supplier should provide all complete accessories as per the machine requirement					
	6. Operating Environment;					
	Ambient tem temperature: 10°C to 32°C					
	Relative humidity: 30% to 80%					
	7. Utility Requirements:					
	Input voltage supply is single phase 220-240 VAC, 50HZ					
	Voltage Regulator					
	KVA rating matches power consumption of the freezer					

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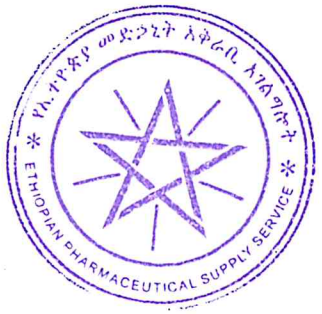
	8. Standards Certificates & Safety Requirements:					
	Should have FDA or CE certification					
	Should meet electrical safety specification as per IEC class I, it, types BF &CF					
	Should meet general requirement for basic safety & essential performance of the medical electrical equipment as per IEC 60601-1-1 I :20 I 0 ,Specifically; [EC 60601-2-16 & IEC 60601-2-39					
	9. Installation/Training/Commissioning:					
	The supplier must be install, commissioning and maintain the machines by free of charges for three years period.					
	The supplier must give consecutive technical training for Blood Bank Service staffs as applicable					
	10. Warranty/ Aftersales service:					
	Installation and user and technical training are mandatory and after sales service of the product must be provided with free of charges.					
	The supplier must be provide minimum of three years warranty including labour and spare part from the date of commissioning.					
	The Supplier should clearly set out a full maintenance and servicing schedule with no costs during warranty period.					
	Suppliers must identify in advance a schedule of planned preventative maintenance (PPM) and provide this to the Laboratory Manager at the EBTBS Testing site. This must include a list of the dates for each visit and what will be done at each visit within a week of installation.					
	All work involving the use of a modem or other electronic data link must be approved in writing by an authorized EBTBS officer before proceeding.					
	The Supplier must provide full records of service/PPM, calibration and equipment upgrades. These must include:Logs of all work carried out during on-site visits or during a modem/data link to the equipment, listings of all equipment/spares used and of changes/upgrades made (including those made by modem/data link) and, an itemized PPM/Service Check-list.					
	Records must be completed, signed and dated by the Supplier's representative during the visit and a copy handed to the EBTBS authorized officer.					
	The Supplier must carry out documented installation qualification of any new items of equipment installed and/or changes made to existing equipment.					
	After PPM or equipment repair the Supplier must verify that all affected equipment is fully operational before departing the premises.					
	The EBTBS management must be notified of any equipment that is not operational or requires further remedial action, calibration or validation post service/repair.					
	Suppliers must provide written advice of hygiene standards required within the environment the instrumentation is being installed.					
	All records will remain the property of the blood bank					
	If an "in house" calibration of the instrumentation is required, the Supplier must provide written instructions including full methodology, associated equipment and documentation, required frequency and expected outcome.					
	Response times to notification of breakdown must be within 24 hour.					
	11. Documentation:					
	should submit operational and technical Manual in English					
	Certificate of calibration and inspection from factory.					
	12. Packaging and Labelling;					
	Packing of all the goods must be clearly marked and securely packed. Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.					
	Additional packing and labeling requirements should bear in each package					

	Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)					
	Tender and Purchase Order No.					
	UMDNS Name and Model of the product					
	PO Box 25-11-276-32-65					
	Tel: +251-11-276-32-65					
	Fax: +251-11-275-25-55					
	Addis Ababa					



1. The requested Cold box 20L Capacity refers to the storage capacity of the cold box not the gross volume.
2. The output pressure for the oxygen concentrator should be not less than 15PSI Permitting use of log cannula.