UNOPS

Clarifications to RFQ

RFQ Ref No: UNOPS-Ukraine-UPTF-2023-G-003 - Provision of Medical Equipment for Blood Tansfusion Stations for Ukraine

Clarification Response Document 02

April 10, 2023

RFQ Reference: UNOPS-Ukraine-UPTF-2023-G-003

UNOPS

TYPE OF GOODS: Request for Quotations for the Provision of Medical Equipment for Blood Transfusion Stations for Ukraine

Attention to All Bidders:

Clarification Request 06: Kindly clarify the following below:

The tender requirements indicated for lot 1 are fully corresponding to the centrifuge Hanil Component 12 R. This centrifuge is registered in Ukraine under safety class I that doesn't allow to operate with the blood for transfusion according RESOLUTION of CABINET OF MINISTERS OF UKRAINE No. 753 'On the approval of the Technical Regulation on medical devices' dated October 2, 2013 (Rule/Clause 11 – Non-invasive devices that change the biological or chemical composition of blood, body fluids or other fluids intended for administration: If the treatment takes place by filtration, centrifugation, gas or heat exchange, these products belong to class IIa and require the procedure of conformity assessment). But the centrifugation of the whole human blood is the main purpose of use for the end beneficiary. If the treatment takes place by filtration, centrifugation, gas or heat exchange, these products belong to class IIa.

To expand the circle of potential participants and include the manufacturers of medical devices of II a/b safety class or more, we kindly ask you to include the changes into the following:

- point '1.9 Adjustable timer range' - up to 99m 59sec or continuous work;
- point 1.12 'Program memory' - at least 89 profiles;
- point 4.1 'Power supply' - 210~240 V 50 Hz, single phase or 380-400 V 50 - 60 Hz 3-phase, plug compatible with Ukrainian standards and
- point 4.2 'Maximum power with aerodynamic fairing (cowling): no more than 9,7 kVA.'

As we can see in Form C Lot 4 information, the net and equipment of the beneficiary is capable to work under such conditions.

4) Lot 4, Form C.
The tender requirements indicated for lot 4 are fully corresponding to the Ragil 2 by Gillardoni.

To expand the circle of potential participants and include the European manufacturers, we kindly ask you to include the changes into the following:

- point '1.11 Amperage setting available' 5 mA – 20 mA, or fixed at 25 mA;
- point '1.12 Water cooling for X-ray generator' - piped water at least 10L/min or integrated close loop cooling;
- point '1.4 Rotating canister configuration that guarantees dose homogeneity.' - or two X-ray tubes that surround the canister and guarantees dose homogeneity.
- point '1.16.1. LAN or WiFi.' - or additional USB-port for data transferring.

- point '1.17. Minimum 15 programs preconfigured by manufacturer' - or the timer setting programed.
- point '1.19. Scales and optoelectronic sensor reset and automatic calibration with every procedure.' -
- point '3.3. Bar-code reader and built-in label printer.' - at least Bar-code reader
- point '15.1 On-site delivery and installation to the recipient institution is included. Installation shall include connection to the Laboratory Information System when available.' - On-site delivery and installation is included. With or without connection to the LIMS. The info can be downloaded to a USB key and transferred to a desktop computer.

We are hoping for your support and understanding in this matter.

UNOPS Clarification Response 06: Kindly be advised that:

Dear Sir or Madam, we would like to get as much participation as possible. Please find our answers to your requirements below:

Lot 1 - Blood bank centrifuge:

- *Original requirement: 1.9 Adjustable timer range: up to 99h 59m.*
- *Change requested:* point '1.9 Adjustable timer range' - up to 99m 59sec or continuous work; Continuous work is a more restrictive requirement since it does not limit the operational time of the equipment. This change can't be accepted as required. Please note that the original requirement is 1.9 Adjustable timer range: up to 99h 59m.

- *Original requirement: 1.12 Program memory for at least 100 profiles.*
- *Change requested:* point 1.12 'Program memory' - at least 89 profiles; Accepted. Please refer to RFQ UNOPS-Ukraine UPTF-2023-G-003_Amendment 2.

- *Original requirement: 4.1 Power supply: 210~240 V 50 Hz, single phase, plug compatible with Ukrainian standards.*
- *Change requested:* point 4.1 'Power supply' - 210~240 V 50 Hz, single phase or 380-400 V 50 - 60 Hz 3-phase, plug compatible with Ukrainian standards. This requirement will be amended as stated for lot 4 to grant more flexibility. Please refer to RFQ UNOPS-Ukraine UPTF-2023-G-003_Amendment 2: 4.1 Power supply: 220 ±10% V 50 Hz, single phase, plug C type or 380V±10% 50 Hz, three-phase.

- *Original requirement: Maximum power with aerodynamic fairing (cowling): no more than 6 kVA.*
- *Change requested:* point 4.2 'Maximum power with an aerodynamic fairing (cowling): no more than 9,7 kVA.' The original formulation "4.2 Maximum power with an aerodynamic fairing (cowling): no more than 6 kVA." must be preserved according to the beneficiary's needs. Since the launch of the Russian Federation's full-scale invasion of Ukraine, Mykolaiv has experienced frequent electricity cutoffs, including due to Russian missile

strikes on critical infrastructure. As a result, Blood transfusion station is often forced to switch to a power supply from its backup diesel generator to ensure the uninterrupted performance of technological processes. If the maximum power indicator is increased to 9.7 kVA (an increase of over 60%). In that case, this will significantly increase the load on the diesel generator and a corresponding significant increase in generator fuel cost. Given these circumstances, the beneficiary considers this requirement critical and insists on preserving the original formulation.

Lot 4 - Irradiator:

- *Original requirement: 1.11 Amperage setting available: 5 mA – 20 mA, 5 mA step*
- *Change requested:* point '1.11 Amperage setting available' 5 mA – 20 mA, or fixed at 25 mA. The proposed amendments introduce a restrictive requirement reducing the circle of potential suppliers, since the new requirement fixed at 25 mA is stricter than the current one "1.11 Amperage setting available: 5 mA – 20 mA, 5 mA step". The final beneficary insist on preserving the requirement's original formulation. With the intended use of the equipment in mind, the range of 5 mA – 20 mA with a 5 mA step is perfectly sufficient to perform the technological processes at the Blood transfusion station.

  We also wish to stress that increasing the maximum amperage to 25 mA will lead to increased power consumption. As explained before, when central power supply is disrupted (and the backup diesel generator has to be used to ensure the uninterrupted performance of technological processes at the Blood transfusion station), this will increase the load on the diesel generator and, correspondingly, generator fuel costs.

  In view of these circumstances, the final beneficiary see this requirement as critical and insist on preserving the original formulation.

- *Original requirement: 1.12 Water cooling for X-ray generator: piped water, water flow speed no less than 5 liters/min.*
- *Change requested:* point '1.12 Water cooling for X-ray generator' - piped water at least 10L/min or integrated close loop cooling. The integrated closed loop cooling will increase the level of noise produced by the equipment, therefore the final beneficiary insist on using piped water as the cooling agent, which is also more efficient. Plus, considering the ergonomics of the equipment operator's work, the increased noise level will cause greater tiredness for the operator and potentially increase the number of mistakes in operating the equipment. Another critical aspect is that if the water flow parameter is increased to 'no less than 10 l/min, this will render the equipment unusable when the flow in the centralised water supply system is weaker, and cause breakdowns in the Blood transfusion station's technological processes.

  The beneficiary insist in preserve the original formulation "1.12 Water cooling for X-ray generator: piped water, water flow speed no less than 5 liters/min", which will enable operation with weaker central water supply system flow and ensure the uninterrupted nature of technological processes at the Blood transfusion station.

- *Original requirement: 1.4 Rotating canister configuration that guarantees dose homogeneity.*

- *Change requested:* point '1.4 Rotating canister configuration that guarantees dose homogeneity.' - or two X-ray tubes that surround the canister and guarantee dose homogeneity. It is critical to note that only the rotating canister configuration ensures maximum dose homogeneity. The final benefiary insist in preserve the original formulation, since the rotating canister configuration is used by all leading manufacturers of such equipment to ensure due homogeneity. Therefore, the technical specification remains as original formulated: "1.4 Rotating canister configuration that guarantees dose homogeneity."

- *Original requirement: 1.16.1. LAN or WiFi.*
- *Change requested:* point '1.16.1. LAN or WiFi.' - or additional USB-port for data transferring. Please refer to RFQ UNOPS-Ukraine UPTF-2023-G-003_Amendment 1.

- *Original requirement: 1.17. Minimum 15 programs preconfigured by manufacturer.*
- *Change requested:* point '1.17. Minimum 15 programs preconfigured by manufacturer - or the timer setting programmed. Please refer to RFQ UNOPS-Ukraine UPTF-2023-G-003_Amendment 1.

- *Original requirement: 1.19. Scales and optoelectronic sensor reset and automatic calibration with every procedure.*
- *Change requested:* point '1.19. Scales and optoelectronic sensor reset and automatic calibration with every procedure.' Please refer to RFQ UNOPS-Ukraine UPTF-2023-G-003_Amendment 1.

- *Original requirement: 3.3. Barcode reader and built-in label printer.*
- *Change requested:* point '3.3. Bar-code reader and built-in label printer.' - at least a Bar-code reader. The built-in label printer is more convenient, as it neither requires an additional computer to be connected, nor additional space to be allocated for the printer. Additionally, the built-in printer makes the operator's work more convenient and ergonomic. Beneficiary therefore insist that the original formulation be preserved '3.3 Bar-code reader and built-in label printer.' The ergonomics of the operator's workstation is key to the operator's mistake-free work. We are discussing blood transfusion, and it's the patient's life that is at stake, should a mistake occur.

- *Original requirement: 15.1 On-site delivery and installation to the recipient institution is included. Installation shall include connection to the Laboratory Information System when available.*
- *Change requested:* point '15.1 On-site delivery and installation to the recipient institution are included. Installation shall include connection to the Laboratory Information System when available.' - On-site delivery and installation are included. With or without connection to the LIMS. The info can be downloaded to a USB key and transferred to a desktop computer. This requirement can't be deleted since it eliminates functionality.

Clarification Request 07: Kindly clarify the following below:

Could we also clarify, would a contract on the medical devices (equipment) be recognized as a similar contract, or should it be for the centrifuge only, for example?

UNOPS Clarification Response 07: Kindly be advised that:

A contract of medical devices (equipment) can be recognized as a similar contract.

Clarification Request 08: Kindly clarify the following below:

Form C., Column Technical Specification, item Letter of Authorization from Manufacturer.

Can we confirm this requirement with Authorization from the official distributor in Ukraine? Because the Manufacturer won't issue the authorization to a third party.

UNOPS Clarification Response 08: Kindly be advised that:

Please refer to RFQ UNOPS-Ukraine UPTF-2023-G-003_Amendment 2. We can accept Authorization from the Official Distributor. Please consider that the authorization text must also indicate that the authorized Distributor is jointly committed with the bidder to provide the required post-sales services, guarantees, and training requested. Furthermore, authorization must be accompanied by the document that certifies that the Distributor has official authorization from the Manufacturer to sell/distribute the offered equipment.

Clarification Request 09: Kindly clarify the following below:

5.1. Valid and current product registration issued by the State Service of Ukraine on Medicines and Drug Control (SMDC) in conformance with the Technical Regulation on medical devices approved by Resolution of Cabinet of Ministers of Ukraine No. 753 of 02/10/2013 or Technical regulation on medical devices for in vitro diagnostics approved by Resolution of Cabinet of Ministers of Ukraine No. 754 of 02/10/2013, as applicable.

We will apply for product registration, as soon as the contract has been awarded. Is this admissible for the tender (same as for point 5.2. and 5.3.)?

UNOPS Clarification Response 09: Due to local legal requirements and delivery lead times requirements, it is not possible or admissible for this tender.

Clarification Request 10: Kindly clarify the following below:

12.1 Affidavit from the manufacturer stating the address in Ukraine of the company that will conduct maintenance of the equipment. We will contract with a company for maintenance, as soon as the contract has been awarded. Is this admissible for the tender (same as for point 13.1.)?

UNOPS Clarification Response 10: Due to delivery lead times requirements, it is not possible or admissible for this tender.

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