VOLYN OBLAST STATE ADMINISTRATION
HEALTHCARE DEPARTMENT
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03.01.2019 No. 22/15/2-19 for No. _____ as of _____

To all potential bidders

Subject: Clarifications to the Bidding Documents of ICB-G No. 6.2.2.2 "Procurement of medical equipment and consumables for healthcare facilities of the secondary and tertiary levels (phase 2)"

Dear Sirs and Madams!

In response to questions submitted by potential bidders we provide the following clarification in the form of questions and answers

Questions and answers No.1

Lot No.7 Consumables for stenting and coronarography

<table>
<tr><th>Questions</th><th>Answers</th></tr>
<tr><td>The quantity of each item of consumables in the set is calculated according to the formula «quantity»* «the quantity» specified in the batch of the supply «a set for stenting with uncovered stents».

Determination of the proportional quantity of each typical size of components of the stenting kit will be carried out when signing the contract.

<table>
<tr><th>Name</th><th>Quantity</th></tr>
<tr><td>Puncture needle</td><td>1</td></tr>
<tr><td>Kit for coronary angiography for transfemoral access</td><td>0,4</td></tr>
<tr><td>Kit for coronary angiography for transradial access</td><td>0,6</td></tr>
<tr><td>Guiding catheter</td><td>1</td></tr>
<tr><td>Y- connector, needle, twister (PTCA set)</td><td>1</td></tr>
<tr><td>Coronary guide</td><td>1</td></tr>
</table>
</td><td>The quantity of each item of consumables in the set is calculated according to the formula «quantity»* «the quantity» specified in the batch of the supply «a set for stenting with uncovered stents». Determination of the proportional quantity of each typical size of components of the stenting kit will be carried out when signing the contract. The total number for each of the sets for stenting and coronary angiography is defined in para 1.1 of the ITB of the Bidding documents.</td></tr>
</table>

Coronary balloon catheter	1
Post-dilution balloon	0,3
Stent system without curative coating	1
Inflation set (indeflator)	1
Device for closing vessels	0,2
Aspiration catheter	0,3

Do we understand correctly that the specified quantity which is indicated in the column "quantity" opposite the "name", is the coefficient to the total number specified in p.1.1 of the ITB? That is, for example, ***Kit for coronary angiography for transfemoral access*** as part of ***A set for stenting with uncovered stents*** should be 250*0,4=100 pcs?

Or, for example, ***Kit for coronary angiography for transradial access*** as part of ***A set for stenting with covered stents*** should be ***500*0,6=300*** pcs***?***

Products that should be included in the kits you specify are self-sufficient medical products, and therefore they were certified like individual items, rather than sets, and it would be more appropriate to ship them as individual items that match the name of the registered products. Will the Customer not object if the supply of the indicated equipment will be carried out not in sets (formed quantitatively and qualitatively by the Customer), but by piece, with the total quantity stipulated by the Customer's requirements, possibly for the convenience of the Customer, by separate delivery notes?	It can be both shipment as sets and as individual items, of total quantity stipulated by the Customer's requirements.

Lot No.9 A medical gas supply system.

Questions	Answers
Para. 1 «Oxygen generator of stationary type, medical»	
Para 1.3. The oxygen generator has to provide working oxygen concentration in % of not less than 95% - to change into «The oxygen generator has to provide working oxygen concentration in % of not less than 93%».	In the sub para. 3 of the Bidding documents it is mentioned «The oxygen generator has to provide working oxygen concentration of not less than, % 93%». There is no information about 95% in the documents
Para 1.5. Receiver capacity, not less than 900 L - to change into «Receiver capacity, not less than 500L».	In the sub para. 5 of the Bidding documents it is mentioned «Receiver capacity, not less than 450 L.». There is no information about 900L in the documents
Para 1.17. The generator set has to include a buffer tank for generated oxygen made of	In the sub para. 17 of the Bidding documents it is specified «The generator set has to include a buffer

Questions	Answers
stainless steel, at least 0,9 m3 - to change into «The generator set has to include a buffer tank for generated oxygen made of stainless steel, at least 0,5 m3».	tank for generated oxygen – Available». There is no information about the volume and material of the tank, since it is clear that this should be oxygen capacity.
Para 1.20. Size and weight of the generator not more than: 1610x840x2220 mm, 880 kg - to change into «1250x950x2200mm, 1100kg».	In the sub para. 20 of the Bidding documents it is specified «Size and weight of the generator not more than: 1070 mm x 860 mm x 1980 mm – 800 kg». There is no information about the size1610x840x2220 mm.
Para. 2 «Central compressor station for medical gas supply system»	
Para 2.3 «Russified» - To delete.	In the sub para. 3 of the Bidding documents it is specified «Compressors operation control unit has to have an indication system which displays malfunction during operation and controls compressor parameters: grease temperature, air pressure in the receiver, temperature of the dew point of the air at the outlet of the built-in refrigeration dehumidifier, number of hours that the equipment worked, and inter-service intervals – Available». In this paragraph the word "Russified" is not mentioned.
Para 2.15. - To state in the following wording- « Availability of air filtration system».	In the sub para. 15 of the Bidding documents characteristics for the air filtration system are specified.
Para. 6 «Medical gases pendant (anesthesiological)»	
Para 6.10. - Load on the pendant, not less than 150 kg - to change into «Load on the pendant, not less than 100 kg».	In the sub para. 10 of the Bidding documents it is specified «Load on the pendant, not less than 580 kg». 150 kg are not mentioned in this para.
Para. 7 «Medical gases pendant (surgical)»	
Para 7.10. - Load on the pendant, not less than 150 kg - to change into «Load on the pendant, not less than 100 kg».	In the sub para. 10 of the Bidding documents it is specified «Load on the pendant, not less than 580 kg». 150 kg are not mentioned in this para.

Lot No. 3 System for intravascular measurement of blood flow reserve in the coronary arteries

Questions	Answers
Please make changes to the technical specification of LOT No.3 "System for intravascular measurement of blood flow reserve in the coronary arteries" in connection with the requirements of the world community for the application of ultrasound diagnostics for fluometry during coronary artery bypass grafting (CABG - Coronary Artery Bypass Grafting). The list of changes is provided below: 1. The work of the system of ultrasound evaluation of the quality of intraoperative blood flow (or system for fluometry) should be based on the actual measurement of blood flow in the sterile conditions of the operating field 2. The system should not be contradicted to clinical application during aortic-coronary bypass surgery 3. The data of measurements should be processed and submitted both in absolute values of blood flow in ml/min, and in relative indicators, which confirm the quality of blood flow: the relative value of resistance in the basin of the vessel, the dependence of the amount of blood flow from the phase of the heart cycle 4. The system should allow the storage of data from previous measurements, with the possibility of printing and storing them on	The requirement stays unchanged. This measurement is used to measure the blood flow reserve by intravascular transducers when performing coronary angiography and stenting, and not for measuring blood flow velocity on shunts when performing open operations.

5. The size of the transducers should vary from 1.5 mm to 16 mm, with the transducers to be used in aortic-coronary artery bypass surgery should be of the size: 1.5; 2; 3; 4; 5 mm for accurate selection depending on the size of the shunt 6. Blood flow measurement transducers should be suitable for resterilization and have a usage limit of at least 50 times. 7. The system should be equipped with the transducers for measuring of blood flow in vessels of different diameter	

Lot No. 6 Laboratory equipment and consumables for the determination of biochemical parameters

Questions	Answers
пункт 1. Item 1. "Automatic biochemistry analyzer with ion selective block (type 1)" - Detailed requirements number 7 "Study of the STAT-samples more than for 5 minutes": Please confirm that you mean "not more than 5 minutes".	"The possibility to detect the STAT-samples of no more than 5 minutes" is meant
Item 8. "Automatic biochemistry analyzer (type 2)" - Detailed requirements number 7 "Possibility to store reagents on tray in cooled and uncooled positions": Please confirm that you don't need to store reagents on tray in uncooled position because this may alter the characteristics of the reagents	Reagents should be stored properly: - reagents that require cooling should be kept refrigerated; - reagents that do not require cooling may be stored without cooling
Item 2 "A set of reagents and control and calibration solutions for determining the level of cholesterol, triglycerides and lipoproteins of high and low density for an automatic biochemistry analyzer with ion selective block (type 1) for 100 determinations": Please clarify the correct quantity of reagents you need, if you need reagents for 100 determinations or if you need 300 sets of reagents	The delivery of the set of reagents is required for no more than 100 determinations with the corresponding number of control and calibration solutions, and there should be 300 of those sets totally
Item 3 "A set of reagents and control and calibration solutions for determining the glucose level for an automatic biochemistry analyzer with ion selective block (type 1) for 100 determinations": Please clarify the correct quantity of reagents you need, if you need reagents for 100 determinations or if you need 300 sets of reagents;	The delivery of the set of reagents is required for no more than 100 determinations with the corresponding number of control and calibration solutions, and there should be 300 of those sets totally
Item 9: "A set of reagents and control and calibration solutions for determining the level of cholesterol, triglycerides and lipoproteins of high and low density for an automatic biochemistry analyzer (type 2) for 100 determinations": Please clarify the correct quantity of reagents you need, if you need reagents for 100 determinations or if you need 20 sets of reagents;	The delivery of the set of reagents is required for no more than 100 determinations with the corresponding number of control and calibration solutions, and there should be 20 of those sets totally
Item 10: "A set of reagents and control and calibration solutions for determining the glucose level for an automatic biochemistry analyzer (type 2) for 100 determinations": Please clarify the correct quantity of reagents you need, if you need reagents for 100 determinations or if you need 20 sets of reagents;	The delivery of the set of reagents is required for no more than 100 determinations with the corresponding number of control and calibration solutions, and there should be 20 of those sets totally

Item 7: "Troponin test strips" o Please clarify if you need 4780 pcs of Troponin test strips or if the test is intended to serve a mix between Troponin, myoglobin and D-dimer tests as this item is linked to item 6 o In case it should serve a mix of tests, please specify the test strips quantities of each test.	The delivery of test strips is required to determine Troponin
General questions	
Questions	**Answers**
Considering that CIP is the INCOTERM indicated in the BDS in terms of delivery: Please confirm that all taxes and duties will be paid by the Purchaser. If not, please indicate which taxes and other duties do we have to include in our offer (e.g. custom duties, VAT, local taxes, other – in this case please specify which ones) and indicate the relative percentage.	Requirements regarding formation of the tender offer price is indicated in ITB 14 Bid Prices and Discounts. Local VAT will not be shown in the bid prices and shall be paid by the Purchaser as an addition to Bid/ Contract Price.
Section III. Evaluation and Qualification Criteria, (b) If Bidder is not Manufacturer. In consideration of the fact that we are not a Manufacturer and that there will be several manufacturers involved in the offer due to the different nature of required items, and that the products offered are high quality and latest technology: Please confirm that a self-certification of the Manufacturers on their letterhead stating that they meet the Experience and Technical Capacity, i.e. that they have at least 7 (seven) years of experience in manufacturing of similar goods, is accepted as a demonstration.	According to the provisions of (b) if Bidder is not a Manufacturer, 3.1 Postqualification Requirements (ITB 36.1), 3. Qualification (ITB 36) of the Section III Evaluation and Qualification Criteria. The customer will review any documental confirmation of bidder's qualification.
Section VII. Schedule of Requirements states that the execution period is expected to be between 30 days and 120 at latest. Do we have to consider also customs clearance times within the period of implementation?	The product must be delivered not earlier than 30 days but not later than 120 days which includes time required for custom clearance.
Please confirm that, in case of award, the payment will be made using the same currency of the offer.	Payment requirements are specified in GCC 16.4, Section IX, Special Conditions of Contract.
Please specify if spare parts have to be quoted. In case of positive answer, please indicate if we have to fill a price schedule only for the purpose of spare parts or if we can indicate a lump sum in the "Price Schedule: Goods Manufactured Outside the Purchaser's Country, to be Imported".	Requirements regarding necessary list of goods are specified in ITB 1.1. All Bidders shall refer to Description of Goods provided in Price Schedule Forms, Section IV. Bidding Forms and Schedules provided in Section VII. Schedule of Requirements.
Section VII - Schedule of requirements, 3.6 Post warranty service: please specify if we only have to confirm availability of this service	Requirements regarding after-sales service are specified in ITB 17.2 (b)

locally or if we shall include this service in the price of our offer. In this case, please indicate for how long the service is requested.	
GCC 13.1: For goods supplied from abroad, (viii) "Original of Certificates of Metrological calibration test […] covered by the Ukrainian State metrological supervision": please specify for which items this certificate is requested Third from bottom paragraph: "The documents shall be in Ukranian language": For goods supplied from abroad, please confirm that documents could be in English language	Measuring equipment that came from outside Ukraine should be entered in the State Register of Ukraine, and in the technical documentation it is determined in Ukrainian or Russian language that they belong to the means of measuring equipment, with certificates of State registration, metrological certification or verification in Ukraine, and the frequency of verification, respectively to the methods developed by the bodies of the State Standard. For Goods supplied from abroad the documents shall be in the language of the Contract with the Ukrainian translation

Please inform us about the receipt of this document '**Questions and answers No.1**' to e-mail volyn.wbproject@gmail.com

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