Procurement of Medical Devices for Clinical Centre Dr Dragiša Mišović

IOP/6-2017/RD

Clarification no. 7

Issued on 22.09.2017.

Question 1:
The tender documents for the public procurement of medical devices for clinical centre Dr Dragisa Misovic no. IOP/6-2017/RD prescribe the payment model according to the DAP parity (insured and delivered at the place of delivery, with no value-added tax and import duties), please answer the following questions we have:

Can a Bidder as one of the participants in a **joint venture** send an invoice to the Contracting Authority for the part of the goods they deliver?

Answer 1:
The answer is yes.

Question 2:
Considering that Purshaser gave explanation in Clarification 2. for the public procurement procedure number IOP/ 5-2017 / RD regarding the issue of Tax Exemption, whether the answer in Clarification no.2 can also be applied in this public procurement procedure no. IOP/ 6-2017/RD

Answer 2:
The answer is yes. After signing of the contract, the purchaser will provide the supplier by documents on the basis of which the supplier can be examped from income customs and VAT in the purchaser country.

Question 3:
Lot 8/ICT Infrastructure
Is the Bidder obliged, in addition to delivering the requested information infrastructure, to migrate data and integrate the new system?

Answer 3:
It is necessary to migrate data and integrate it with new solution.

Question 4:

In the public procurement IOP/6-2017/RD, Lot 1 – OP Room, section 13. Temperature Control Unit, under number 4 in Technical Specification Sheet, it is requested: "The warming system capable for heating of infusion fluid and blood through a special set of single-use (up to 3 liters per hour)."
The requested flow rate of "up to 3 l/h", means up to 50 ml of blood/fluid per minute, which might be inadequate in most surgeries where higher blood loss is expected. Higher flow rate would be much more desirable for medical staff and much more benefitial for the patient. Limited flow rate of 3 l/h limits the delivery of warm blood/fluid to the patient in critical moments of the surgery, so it doesn't make any sense from the medical point of view
Would you consider correcting this part of specification so the bidders with wider range of flow rate (e.g. up to 3 l/h or higher) could bid for this lot?

Answer 4:
Suggestion is not acceptable.
The requested device, Temperature Control Unit is intended for patients warming through disposable blankets. The unit is designet to deliver effective forced-air patient warming in order to maintain normothermia. The requested device has additional fluid warming set to enables clinicians to use simultaneously two warming modalities with one piece of equipment: patients warming and fluid and blood warming.

Due to low-flow performance (KVO to 50ml/min) the additional fluid warming set is intended to use in standard surgical procedures where higher blood and fluid loss is not expected. The rapid blood and fluid resuscitation is provided by using fluid warming units and high-flow sets whitch are not required in this tender.

Question 5:

In the tender documents it is said that the price in the bid should be in line with the DAP parity and that the customs import duties and other associated expenses should be presented separately. Please clarify where we should present such expenses (customs duty, VAT and other expenses), since there is no designated column for that in the tender documents? Since we cannot know the other associated expenses in advance (transport, shipping...) can we (and where) express them roughly in percentages?

Answer 5:

See Clarification 5., Answer 1.

Question 6:
We also ask for your confirmation of whether the documents such as catalogues, brochures, instruction manuals, manufacturer's statements as proof of meeting the required technical characteristics can be submitted as copies and extracts or do we have to submit the original documents?
Answer 6:
Yes, copies of these documents are acceptable.
Question 7:
For Lot 1
Must be CE, FDA or TUV approved

We would like to draw your attention to the fact that CE, FDA and TUV certificates are basically 3 different things. The CE mark means that the medical device is manufactured in accordance with the guidelines and following all European and global regulations related to medical equipment. The FDA certificate (by the way, FDA is something similar to the MMDAS just in the USA) is the permit that medical equipment CAN BE SOLD IN THE UNITED STATES OF AMERICA (just like MMDAS's permit for placing on the market means that the goods can be sold in Serbia). TUV is just one certification organization (like there are also SGS, TUV Rheinland, etc.). Accordingly, in order to not discriminate against manufacturers who have registered their products with other organizations and not with TUV, please delete this requirement or write what is it that you specifically need. We do not understand why you need the manufacturer to have the FDA certificate for selling the product in the USA when the hospital KBC Dr Dragisa Misovic is located in Belgrade, Serbia?
Answer 7:

The Purchaser has given the opportunity to a potential Bidder to submit one of the above certificates, depending on the origin of the offered good.

Question 8:

Lot 1

Removable visco-elastic multi-layer component foam with a thickness of maximum 60mm with integrated memory function and sealed against fluids. No velcro fastener for fixation.

Why did you put that the MAXIMUM thickness of the foam is 60mm, when it is widely known that more expensive foams of higher quality have a higher thickness, for example 80 or 90mm? Please change this requirement to minimum 60mm so that the producers who have higher quality operating tables can also participate in the public procurement

Answer 8:

Due to some complicated long operative procedures, the mattress/pad on the operating table has to be at a maximum thickness of 60mm, because the absorbent layer is placed on the top of it (similar to baby nappies), which is for single use and whose thickness varies from 10 - 40 mm. This separation into the fixed pad/mattress (an integral part of the operating table made by the manufacturer of the operating table) and variable, for single use, is the best solution for prevention the transfer of bacteria through contact with fluids, prevention the occurrence of decubitus wounds due to hypostatic exposed parts of the skin, the transfer of multiple-resistant bacterial strains. All of these significantly decreased if patients are not in direct contact with mattress, but through an additional layer that is disposable and has the function of a controlled absorption of liquid.
This facilitates the disinfection of the contact surfaces of the operating table and reduces the time between the two operations necessary to prepare for the next surgical procedure. It should also be noted that the movement of the table during the operation, primarily the change of the Trendelenburg / anti Trendelenburg slope and the lateral inclination, puts a limitation on the patient's distance from the basic-fixed structure of the operating table (max. 9-10 cm) in order to prevent patient to slip / catastrophic complications in general anesthesia during these manipulations.
By market research, it has also been established that several renowned bidders meet this requirement, and the Purchaser remains at his request.

Question 9:

Lot 1

The shape of main light and satellite light should be triangular (for better laminar flow above the surgical field).

In order for the other word-renowned high quality manufacturers except for the manufacturer SIMEON to be able to take part in the public procurement, please completely remove this utterly malicious and extremely discriminatory description or write that you will also accept the lights of circular shape. Namely, your description "For better laminar flow above the surgical field" is clinically inaccurate and is based exclusively on the catalogue of the manufacturer SIMEON. We

note that all GLOBAL MANUFACTURERS "Maquet, Trumph, Draeger, Mindray, Steris, even the famous Dr. Mach" have lamps of circular shape. Only the manufacturer SIMEON represented by PTM Sabac has lamps of triangular shape. We'd like to draw your attention to the fact that all manufacturers already have a built-in solution for "better laminar flow", and that is not the triangular shape of the lamp. Please align the descriptions with your REAL needs AND FINANCIAL CAPACITIES so that you could buy the best equipment for the allocated money, and not triangular toys.

Answer 9:
The triangular shape of the lamp, unlike the round one, allows the main and auxiliary light to fit into a shape that makes the light system more compact and light beams much closer to each other. The flat in which the lights are positioned is unique and there is no overlap of the light. In view of the above, the triangular shape reduces the shadow and loses the effect of the double shadow, the lighting field is more compact and more intense.
By fitting the lamps, in the case of a triangular shape, we get the smaller surface and smaller disturbing the natural or forced air flow. The shape enables a completely effective air flow.

Question 10:
Lot 1
Please submit photos and technical descriptions for the premises where the OR furniture will be placed, so that we can send you an adequate and satisfactory bid. In order to avoid the scenario when after the delivery it turns out that the premises are not adequate and there is no room to install it (for example if something is either shorter than the designated space or longer). Because in that case if you do not deliver the adequate drawings and technical descriptions, the manufacturers will not be responsible if something needs to be changed, etc.
Answer 10:
Potential Bidders have opportunity for onsite visit. Please send e-mail to office@dragisamisovic.bg.ac.rs in order to schedule an appointment

Question 11:
Please explicitly specify which goods from Lot 1 need to be registered with the ALIMS, and which do not.
Answer 11:

For offered medical devices, it is necessary to submit documentation (licence) of current valid registration in ALIMS -R. Serbia. This requirement applies to all offered medical devices unless otherwise specified in Technical specification.

Concrete for Lot 1 such evidence is not required for:

Position 1.8-all items, from 1.8.1 to 1.8.11

Position 1.10 - Non – contact dispensers for hand washing, carriers paper and soap (from 1.10.1 to 1.10.3)

Position 1.11 - Automatic wrapping machine for shoes

Position 1.22 – Medical Air plant

Position 1.27 - Endoscope drying cabinet

Question 12:

Lot 1

Transport ventilator – Please confirm that you want a transport ventilator without a screen? As the description doesn't mention that you want the screen and the size of the display.

Answer 12:

Transport ventilator should have display. The size of display is not defined because it has not fundamental importance for Beneficiary.

Question 13:

Lot 1

1,8,1 Instrument washing sink

The instrument washing sink has two bowls. How deep and what are the dimensions of the bowls? Where are the faucets located? Does it have a door, and if so what kind (sliding or regular)? Do you need to have a lower shelf?

Answer 13:

Dimensions of the sinks are approx. 50x50x30 cm. The battery should be placed in the middle, between the sinks. It should have one lower shelf. Cabinet is with two sliding doors.

Question 14:

Lot 1

1,8,9 Operating room cabinet

Cabinet with a sliding glass door, this means that one half of the cabinet will always be unavailable? Is this really what you want? The frame for sliding glass doors on inox cabinets is almost as a rule the aluminium inox look (Industrial-made special-purpose mouldings) do you agree with that?

Answer 14:

The Purchaser stay with the sliding door requirement, because of easier manipulation (the side needed at that moment opens)

Question 15:

Lot 2

We would like to draw your attention to the fact that you as the Contracting Authority cannot decide approximately what requires a certificate from the ALIMS and what doesn't. Some of the items you listed as not requiring the certificate have already been registered with the Alims and you as the Contracting Authority cannot arbitrarily choose what to buy with the certificate and what not to. There is a law for that. Please align your description with the law or we will be forced to seek protection for our rights with the commission for protection of rights.

Answer 15:

By inspecting the list of registered medical devices on the ALIMS website and by examining the market, we listed equipment that is subject to registration and equipment that is not subject to registration.

If you have otherwise information, please provide us with specific information in order to correct it.

Question 16:

Lot 3

Hospital bed with hydraulic functions, designed for adult patients

We would like to note that the year is 2017 and that beds with HYDRAULIC functions were being purchased in 1980. Please also allow the offers of beds with electrical functions which are keeping up with the 21st century. Also have in mind that with the beds with hydraulic functions, after one year of use the hydraulic oil from the motor can spill out (it all depends on whether the patients using the bed are lighter or heavier, whether the height of the bed is often adjusted, etc.). So our warm recommendation is, since you already have enough allocated money, to purchase exclusively electrical beds.

Answer 16:
See Addendum no. 2

Question 17:
Bed palette filled with a steel wire mesh or better

Please reconsider this request, because if it remains like this you will get beds with WIRE MESH which will be used in 2017 by a renowned tertiary level institution? All manufacturers have the wire mesh bed base along with HPL base and ABS base. We suggest the minimum of ABS base or better, in order to get beds that will really follow all the European and global standards, and not beds that can be manufactured in a garage.

Answer 17:
See Addendum no. 2

Question 18:
Lot 3
Varnished, foldable side rails

Please write what kind of side rails you want, made from metal or from ABS.

Answer 18:
See Addendum no. 2

Question 19:
Lot 3
We would like to draw your attention to the fact that you as the Contracting Authority cannot decide approximately what requires a certificate from the ALIMS and what doesn't. Some of the items you listed as not requiring the certificate have already been registered with the ALIMS and you as the Contracting Authority cannot arbitrarily choose what to buy with the certificate and what not to. There is a law for that.

Please align your description with the law or we will be forced to seek protection for our rights with Republic Commission for Protection of Rights in Public Procurement Procedures

Answer 19:

By inspecting the list of registered medical devices on the ALIMS website and by examining the market, we listed equipment that is subject to registration and equipment that is not subject to registration.

If you have otherwise information, please provide us with specific information in order to correct it.

Question 20:

3,4,7	Locker for pharmacy

Please give us an approximate image of this item so that we can offer the appropriate item, because it is vague the way it is written.

Answer 20:

The Purchaser remains at his request. Beneficiary's needs are clearly and precisely defined.

Question 21:

3,4,9	Examination bed

You called this item examination bed but the description describes a stretcher for transfer of patients. Please confirm if you want offered and potentially delivered a stretcher for transfer of patients and not a traditional examination bed.

Answer 21:

If a potential Bidder has in his offer equipment that complies with the specified technical specifications, it may be offered regardless of what it is called. In Beneficiary's project, that position is defined Examination bed.

Question 22:

3,4,15	Beds washing station

Why didn't you put this in LOT 2 for sterilization when it is intended for washing and disinfection of clogs and trolleys from operating rooms?

Answer 22:

The name of position says "Beds washing station."
The Purshaser remains at his request as the device will be used for washing the beds.

Question 23:

3.8	Examination bed

The title here also says examination bed and a stretcher for transfer of patients is described. Please confirm if you want offered and potentially delivered a stretcher for transfer of patients and not a traditional examination bed.

Answer 23:

If a potential Bidder has in his offer equipment that complies with the specified technical specifications, it may be offered regardless of what it is called. In Beneficiary's project, that position is defined Examination bed.

Question 24:

According to the published procedure IOP/6-2017/RD, LOT 4-Auxiliary surgical devices,

in the tender documents in Serbian on page 29 – 19.1 (b) it is said that after sales servicing is needed, and on page 35 - section e) Technical Capability, the following servicing capacity is required: Manufacturer's After Sales Authorization (for Service Company), it is said that manufacturers shall provide after sales service for equipment by the service company registered in the Republic of Serbia, the minimum number of qualified persons in the servicing company – 1 (one) and that the service company shall have the ISO 9001 certificate, then in Manufacturer's After Sales Authorization on page 46 – we hereby authorize to provide to maintenance, repair spare parts-stocking and warranty obligations prescribed in the Conditions of Contract and/or Technical Specifications on our behalf.

our question is:

The equipment that is manufactured as a sealed monoblock (USB controller for nebulizer) and which as such has no serviceable parts and for which the manufacturer did not foresee any servicing interventions, in the event of a malfunction, it is replaced in its entirety. As it is, in the requirements above from the tender documents, explicitly insisted on servicing, would the Contracting Authority accept the Manufacturer's statement saying that the mentioned equipment is not subject to servicing?

Answer 24:

It is acceptable for the Purschaser to submit Manufacturer's statement saying that the mentioned equipment is not subject to servicing

Question 25:

In the tender documents, the procurement in question is subdivided into 8 lots (Lot 1 – Lot 8). **Lot 7**, concerning the IMAGING equipment has a total of 17 items.

Question 1: In Lot 7, the IMAGING equipment, the item **ID 7.8 Digital remote controlled multi-purpose Digital Fluoroscopy/Radiography X-Ray System with Dynamic Flat Panel Detector**

Line 21 lists the technical requirement *"Motorized lateral movement: 24 cm"*
We kindly ask the Contracting Authority to amend, i.e. change this requirement so that is says *"Motorized lateral movement: min. 24 cm"*
All other lines list the minimum technical requirements that the bidder should fulfil, therefore we also believe that this was the intention of the Contracting Authority for this item and that the word min. was omitted by accident.

Answer 25:

Suggestion is acceptable.

Question 26:

In Lot 7, the IMAGING equipment, the item **ID 7.8 Digital remote controlled multi-purpose Digital Fluoroscopy/Radiography X-Ray System with Dynamic Flat Panel Detector**

Line 23 lists the technical requirement *"Progressive variable imaging chain movement speed"*, and line 24 lists the technical requirement *"min. 150 cm/sec"*.
We kindly ask the Contracting Authority to amend, i.e. change this so that these two positions are one position that says *"Progressive variable imaging chain movement speed min. 150 cm/sec"*
Rationale: We believe that the Contracting Authority accidentally separated the requirement in question into two parts, which are not on their own logically complete and specific.
Also the unit of measure of 150cm/sec is oversized, because no manufacturer in the world can get even close to fulfilling the requirement defined in this way, nor would such a speed make sense for the use in diagnostics. Therefore we believe that the unit of measure of 150 cm/sec was put by accident instead of **mm/sec**, so we kindly ask you to make this change.

Answer 26:

Yes, all is a technical error. Position in line 23 reads as follows:

Progressive variable imaging chain movement speed min. 150 mm/sec.

Public Procurement Commission