

**Procurement of equipment for General Hospital in Loznica
NO. IOP/61-2021/UHI**

**Clarification No. 6
Issued on 1th of November 2022**

Question 1:

Lot 5: Radiology Imaging, Item no. 1 - Ceiling mounted x-ray device

- **In technical specification item 1.3** it is required: "Table top size min. 230x80 cm".
Question 1: Do you accept this requirement to be changed to "Table top size min. 220x80 cm"?

We as distributor of respectable manufacturer of Ceiling mounted x-ray device are unable to submit an offer. For sure small decrease in total table top surface does not make any change or decrease in diagnostic quality, on the other hand this will increase number of potential bidders.

Answer: ID 1.3. It is acceptable to offer: Table top size min. 220x80 cm

- **In technical specification item 1.7** it is required: "Automatic detector charging in bucky".
Question 2: Do you accept this requirement to be deleted?
We as distributor of respectable manufacturer of Ceiling mounted x-ray device are unable to submit an offer. This change will increase number of potential bidders.

Answer: ID 1.7. This request will be deleted.

- **In technical specification item 1.22** it is required: "User Interface: Display of SID, Tube Angle, Column Rotation, Patient Name and Date of Birth."
Question 3: Do you accept this requirement to be changed to "User Interface: Display of SID, Tube Angle, Patient Name and Date of Birth."?
We as distributor of respectable manufacturer of Ceiling mounted x-ray device are unable to submit an offer. For sure small decrease in total tube suspension touch screen user interface does not make any change or decrease in diagnostic quality, on the other hand this will increase number of potential bidders.

Answer: ID 1.22. It is acceptable to offer: User Interface: Display of SID, tube rotation angle and Patient Name and Patient ID or Date of Birth.

- **In technical specification item 1.34** it is required: "Vertical motion control by foot switch".
Question 4: Do you accept this requirement to be deleted?
We as distributor of respectable manufacturer of Ceiling mounted x-ray device are unable to submit an offer. This change will increase number of potential bidders.

Answer: ID 1.34. It will be amendment in the Amendment no. 3.

- **In technical specification item 1.57.** it is required: "In-bin charging, the detectors automatically charge when they are in the bucky housing".
Question 5: Do you accept this requirement to be deleted?
We as distributor of respectable manufacturer of Ceiling mounted x-ray device are unable to submit an offer. This change will increase number of potential bidders.

Answer: This request will be deleted.

- **In technical specification item 1.58** it is required: "Pixel size max. 125 μm ".
Question 6: Do you accept this requirement to be changed to "Pixel size max. 150 μm "?
We as distributor of respectable manufacturer of Ceiling mounted x-ray device are unable to submit an offer. For sure small increase in pixel size does not make any change or decrease in diagnostic quality, on the other hand this will increase number of potential bidders.

Answer: ID 1.58. It is acceptable to offer: Pixel size max. 150 μm .

- **In technical specification item 1.64** it is required: "DQE @ 0lp/mm min. 60% (RQA 5)".
Question 7: Do you accept this requirement to be changed to "DQE @ 0lp/mm min. 50% (RQA 5)"?
We as distributor of respectable manufacturer of Ceiling mounted x-ray device are unable to submit an offer. For sure small decrease in DQE does not make any change or decrease in diagnostic quality, on the other hand this will increase number of potential bidders.

Answer: ID 1.64. It is acceptable to offer: DQE @ 0lp/mm min. 50% (RQA 5)

- **In technical specification item 1.68** it is required: "Image preview times max. 2 sec".
Question 8: Do you accept this requirement to be changed to "Image preview times max. 3 sec"?
We as distributor of respectable manufacturer of Ceiling mounted x-ray device are unable to submit an offer. For sure small increase in preview time does not make any change or decrease in diagnostic quality, on the other hand this will increase number of potential bidders.

Answer: ID 1.68. It is acceptable to offer: Image preview times max. 3 sec.

Question 2:

- **In technical specification item 1.4** it is required: "Tabletop transversal movement range min. 25 cm".
Question 9: Do you accept this requirement to be changed to "Tabletop transversal

movement range min. 24 cm”?

We as distributor of respectable manufacturer of Ceiling mounted x-ray device are unable to submit an offer. For sure 1 cm decrease in tabletop transversal movement range does not make any change or decrease in diagnostic quality, on the other hand this will increase number of potential bidders.

Answer: ID 1.4. It is acceptable to offer: Tabletop transversal movement range min. 24 cm

Question 3:

- In Lot 9 – Hospital Furniture

Item No. 33 is entitled Upholstered chair without backrest - for operating room.

However, in the technical description for ID 33.1 the following requirement is made:

"back rest with antistatic cover"

Since a chair for the OP theatre without backrest is required, we assume that a technical error was made and hereby ask for the correction of the technical description in that part of the requested specification.

Answer: ID 33.1. Request will be changed in the Amendment no. 3 to following: Upholstered seat with antistatic cover, height adjustment from 560 to 790 mm by means of gas spring, with foot ring release, with antistatic cover.

Question 4:

In Lot 6 – Laboratory Pathology

Item No. 20, ID: 20.4 the following requirement is made:

"Exterior made of epoxy painted steel"

Is it acceptable to the Tendering Authority that the exterior be made of polyester coated steel since it does not change the functionality of the freezer itself?

Answer: ID 20.4. It is acceptable to offer: Exterior made of epoxy painted steel or polyester coated steel.

- In Lot 6 – Laboratory Patology

Item No. 20, ID: 20.10 the following requirement is made:

"Castors: 4"

Since laboratory freezers do not have castors, we assume a technical error was made and therefore ask for the correction of the technical description in that part of the technical specification.

Answer: ID 20.10. This request will be deleted.

Question 5:

- Is it acceptable for Lot 6 – Laboratory Patology Item 7, ID 7.1. to offer Countertop workstation with bigger dimensions which is better than requested?

Answer: We confirm that Countertop workstation with bigger dimensions than requested will be evaluated as valid offer.

Question 6:

Lot 6

Item 17- Fridge for storing medicine

1. Is it acceptable for Item 17, ID 17.3 to offer refrigerator with an interior made of stainless steel which is better than requested moulded plastic?

Answer: We confirm that suggested solution will be evaluated as valid offer.

2. Is it acceptable for Item 17, ID 17.10 to offer system without self-closing door?

Answer: This request will be deleted.

Item 18-Blood bank refrigerator

1. Is it acceptable for Item 18, ID 18.3 to offer capacity of 300 l?

Answer: ID 18.3. It is acceptable to offer: Capacity (L): min. 300

2. Is it acceptable for Item 18, ID 18.6 to offer refrigerator with other type of controller, for example Logika3 and 2 Pt1000 probes?

Answer: ID 18.6. It is acceptable to offer: Controller model / probe type: G-214 or Logika3 / PT 1000

3. Is it acceptable for Item 18, ID 18.9 to offer refrigerator with power of 360 W?

Answer: ID 18.9. It is acceptable to offer: Horse Power (HP): 1/8 or Power min. 360W

Item 20 Ultra Low Temperature Freezer - Double Security

1. Is it acceptable for Item 20, ID 20.1 to offer temperature range of -60 do - 86C which is better than requested?

Answer: ID 20.1. We confirm that the suggested temperature range is wider Countertop workstation than requested and will be evaluated as a valid offer.

2. Is it acceptable for Item 20, ID 20.2 to offer capacity of 515l which is better than requested?

Answer: It is acceptable.

Question 7:

1. In the excel file LOT9_HospitalFurniture at the bottom of Technical Specification Sheet the Purchaser defined the following – „Note: The supplier is obliged to make, deliver and mount the required positions. Before the production, supplier is obliged to check all the measurements on the spot. For all positions, unless specified in the description, deviations of up to + -5% in all dimensions are allowed“.

We kindly ask the Purchaser to confirm that this Note is valid only for custom made medical and non-medical furniture and not for all the Items defined in LOT 9.

Answer: Yes, we confirm that note is referring only for custom made medical and non-medical furniture and not for all the Items defined in LOT 9.

2. We kindly ask the Purchaser to confirm that for some non-medical, wide consumption appliances that can be bought online or through many resellers, also, for non-medical furniture which is not custom made (for example, Item no. 137 Fridge 100l, Item no. 147 Bin 30l , Item no. 149 Plastic bin, Item no. 150 Mobile garbage bag holder, Item no. 157 Stove, Item no. 160 TV...) the Bidder is not obliged to submit evidence of (f) Technical Capability defined in Section III i.e. Manufacturer's Sales Authorization, Manufacturer's After Sales Authorization and Service certificate.

Answer: Yes, we confirm.

Question 8.

LOT 1_Item 2

1. ID 2.14 FESS consumables

There are listed different models of shaver blades with a diameter of 4mm, length 12cm and angle of 35 or 40 ° - is it acceptable to offer equivalent dimensions to requested so it reads: Shaver blade diameter 4mm ± 0.5mm, length 12cm±2cm, curvature 35±5°and 40±5°

Answer: ID 2.14. It is acceptable to offer: Shaver blade diameter 4mm ± 0.5mm, length 12cm±2cm, curvature 35±5°and 40±5°

2. ID 2.6 ENT motor control unit

There are listed minimum seven functions of control unit including dermatome which is

handpiece used in plastic surgery for the treatment of the burns – it is not a characteristic of importance for the subject of public procurement, since the video equipment included in LOT 1, Item No 2 is intended for arthroscopy as a part of orthopedic surgery and Functional Endoscopic Sinus Surgery- FESS as a part of ENT is it acceptable to make minor changes in this requirement as follows:

ENT motor control unit with color display - touch screen, with accessories:

Two-Pedal Footswitch

Shaver handpiece for FESS application

Straight suction channel, Integrated irrigation channel

Two motor outputs: Two motor outputs enable simultaneous connection of two motors

Answer ID 2.6. It is acceptable to offer:

ENT motor control unit with color display - touch screen, with accessories:

Two-Pedal Footswitch

Shaver handpiece for FESS application

Straight suction channel, Integrated irrigation channel

Two motor outputs: Two motor outputs enable simultaneous connection of two motors

3. ID 2.7 Roller Pump

Would it be acceptable to offer pump for suction or irrigation for ENT procedure that is already integrated in ENT control unit?

Would it be acceptable to offer the tubes as a sterile set, not just individual parts of the set as stated in technical specification so it reads:

Pump for suction or irrigation for with tubes for FESS application

Answer: ID 2.7. It is acceptable to offer: Pump for suction or irrigation for with tubes for FESS application

Question 9:

LOT 7_Item ID 21

In the LOT 7 for Item ID 21.50 requested technical specification is “Upper frequency (-3dB) min 0.2 – 5000 Hz”. This should not be called Upper but High frequency, and the value cannot be the same as the Lower frequency.

We kindly ask the Purchaser to modify the requirement within the Item 21, ID 21.50 so now it reads as follows: “High frequency (-3dB) min. 30-20000Hz”

Answer: ID 21.50. will be change to following: High frequency (-3dB) min. 30-20000Hz.

Question 10:

Our question is regarding Lot 9_ID 19_Bedside cabinet with overbed table - position 19.7.

In position 19.7 you ask for - Sizes: 450 x 4540 x 750 H (Except Castors) $\pm 5\%$.

We are quite sure that dimension 4540 is a typo mistake.

Please can you check it and make a change.

Answer: Yes, it is technical mistake. Dimension are 450*450*750. We will amend it in the Amendment no. 3

Question 11:

In LOT 9 there are a lot of non-medical devices that are not subject to service and some non-medical devices that are used also in households and can be bought through many local distributors like Plastic bin, Bin, various type of Fridges, TV, garbage bag holder, Tabouret, White writing board, Stove etc.

For those items it is almost impossible to obtain documentation from the Manufacturer, so we kindly ask the Purchaser to allow the Bidder to submit only Catalogues and Data Sheets for those items.

Also, please confirm that it is not necessary to submit ISO 9001 for the Manufacturer of those items.

Answer: We confirm that it is acceptable to submit only Catalogues and data sheets for non-medical items within LOT 9.

Question 12:

"Item No. 6 Radiofrequency surgical generator

Point 6.1 - Is it acceptable for Bipolar frequency to be 4.0MHz (this is superior characteristics than asked) and with maximal output bipolar power of 60Watts?

Point 6.3 - Is it acceptable to have 2 buttons handpiece (cut and coag) since it is an industry standard?

Point 6.4 - Is it acceptable to have 2 buttons handpiece (cut and coag) since it is an industry standard?"

Answer:

Answer ID. 6.1: It is acceptable to offer: Radiofrequency surgical generator with output frequency min 4 MHz Monopolar and min. 1.7MHz Bipolar. Output Power Bipolar min. 60 Watts.

Answer ID 6.3.: It is acceptable to offer: At least 2 - Button Fingerswitch Handpiece.

Answer : ID 6.4.: It is acceptable to offer: Disposable at least 2-Button Fingerswitch Handpiece.

Question 13:

In Lot 9, Item No. 33 is entitled Upholstered chair without backrest - for operating room. However, in the technical description for ID 33.1 the following requirement is made:

"back rest with antistatic cover"

Since a chair for the OP theatre without backrest is required, we assume that a technical error was made and hereby ask for the correction of the technical description in that part of the requested specification."

Answer:

ID 33.1 Will be changed and read as follows: Upholstered seat with antistatic cover, height adjustment from 560 to 790mm or wider by means of gas spring, with foot ring release.

Question 14:

In Technical specification for LOT 9, Item 20, ID 20.11 and Item 21, ID 21.11 it is required that: "The bed complies with all requirements stated in MDD 93/42/EEC; 90/384/EEC"". As MDD 93/42/EEC is replaced with Medical Devices Regulation ((EU) (2017/745) please confirm that it is acceptable to offer the goods that comply with Medical Devices Regulation ((EU) (2017/745))"

Answer: LOT 9, ID 20.11, ID21.11. We confirm it is acceptable to offer goods that comply with MDR 2017/745.

Question 15:

In cases when offered goods are manufactured by the local Manufacturer is it acceptable to submit Manufacturers' technical literature (i.e. brochures, data sheets and catalogues) in Serbian language?

Answer: Yes, it is acceptable.

Question 16:

In Clarification 1, Question 3, point 2. the Purchaser allowed that the Manufacturer's documentation can be submitted only for the main equipment i.e. items listed in the Prices Schedule. In this regard we kindly ask the Purchaser to confirm that ISO 9001 or 13485 should be submitted only for the Manufacturer of the main system (equipment).

Answer:

ISO 9001 or 13485 should be submitted only for the Bidders. Please, see Amendment no. 3. as of 01.11.2022, point 12.

Public Procurement Committee

M. Faurborge