Procurement of Medical Devices for Clinical Centre Dr Dragiša Mišović IOP/6-2017/RD Clarification no.19 Issued on 02.10.2017.

LOT 1, ID 1.7 Surgical Suction Unit

Question No.1

In Tender Documentation following technical characteristic is stated:

1. Flow rate: not less than 90 liters/min

We kindly ask you to replace this item with following:

Flow rate: not less than 40 liters/min

This flow rate is typical for surgery aspirators and in practice is confirmed that is sufficient for purpose of this aspirator. Additionally, most of the producers can offer surgery aspirator with mentioned flow rate so more Tenderers could participate at tender.

Odgovor br.1

Naručilac ostaje pri zahtevanom aspiracionom protoku s obzirom na količinu i vrstu operativnih zahvata koji se sprovode u ustanovi.

Answer No. 1

The purchaser remains by the requested aspiration flow rate given the quantity and the type of the operating procedures carried out in the institution.

Question No.2

In Tender Documentation following technical characteristic is stated:

7. Two polycarbonate autoclavable 5 liter bottles

We kindly ask you to replace this item with following:

Two polycarbonate autoclavable 3 liter bottles.

Most of Tenderers cannot compete since available devices cannot fulfill originally stated requirement.

Odgovor br.2

Naručiocu je prihvatljivo da se ponude aspiratori sa polikarbonatnim autoklavibilnim bocama od minimum 4 litre.

AnswerNo. 2

The purchaser finds acceptable bids with aspirators with polycarbonate autoclavable bottles of minimum 4 liters.

Question No.3

In Tender Documentation following technical characteristic is stated:

10. Suction catheter and conical connector

We kindly ask you to remove this item from the document. All Purchasers of medical equipment are practicing to order catheters and other accessories separately from major device

Odgovor br.3

Ne prihvata se sugestija potencijalnog ponuđača budući da je predmet nabavke oprema koja po instalaciji može odmah da se koristi bez raspisivanja za dodatni potrošni materijal.

Answer No. 3

The suggestion of a potential bidder is hereby rejected since the subject of the procurement is the equipment that can be used immediately after installation without inviting a procurement for expendable material.

LOT 1, ID 1.15.4 Permanent drainages

Question No.1

In Tender Documentation following technical characteristics are stated:

- 3. Vacuum level: 0-55 cm H2O or larger
- 4. Two rods made of polycarbonate, one is graduated 0-60 cm
- 5. Complete mounting system: rail clamp, 1.5 m hose and angled remote probe DIN (German Standard)

for vacuum

- 6. 2 L collection jar is autoclavable (134°C), rail mount, 1 pc
- 7. Catheter holder with polycarbonate tube min. 40cm and rail clamp, 1pc
- 8. Suction tip for drainage, 10 pieces
- 9. Silicone suction hose, autoclavable, 3 meters

We kindly ask you to replace these items with following:

Vacuum level: 0-50 cm H2O (-50 to 0 mbar) or larger

Complete mounting system: rail clamp, 1.5 m supply hose (central gas connection DIN) for vacuum

2 L collection jar or set of 2 collection jars 1L (graduated to 0,7L) autoclavable (134°C), autoclavable

(134°C)

Suction tip for drainage, 10 pieces

Silicone suction hose 1,5 meters

This way will help Purchaser to get higher competitiveness as well as enabling more Tenderers to submit proper quotation.

Odgovor br.1

Prihvatljivo je ponuditi aparat sa vakuumom od 0-30cm H2O ili više i kompletnim sistemom za montažu: šinskom stegom, crevom od 1.5m i DIN priključkom za vakuum (nemački standard), kao i autoklavabilnom bocom od minimalno 1.5litre.

Answer No. 1

It is acceptable to bid a device with the vacuum level of 0-30cm H2O or larger, the complete mounting system: rail clamp, 1.5 m hose and probe DIN (German standard) for vacuum, as well as the autoclavable jar of minimum 1.5liter.

LOT 1, ID 1.15.5 Gas Powered Suction Unit Question No.1

In Tender Documentation following technical characteristics are stated:

- 3. Vacuum level: 0-1000 mbar
- 4. Horizontal rotation of the vacuum gauge from -45° to +45° for a better visibility
- 5. 100 ml or larger safety jar is autoclavable (134°C)
- 6. Complete mounting system: rail clamp, 1.5 m hose and angled remote probe DIN (German Standard)

for oxygen and medical air

Accessories for each unit:

- 7. 2 L collection jar is autoclavable (134°C), rail mount, 1 pc
- 8. Catheter holder with polycarbonate tube min. 40cm and rail clamp, 1pc
- 9. Antibacterial filters, 100 pieces
- 10. Suction tip for drainage, 10 pieces
- 11. Silicone suction hose, autoclavable, 3 meters

We kindly ask you to replace these items with following:

Vacuum level: 0-480 mbar 100 ml or larger safety jar mounting system - rail clamp, 1.5 m gas supply hose(central gas connection DIN) for oxygen or medical air

Accessories for each unit:

2 L collection jar or set of 2 collection jars 1L (graduated to 0,7L) autoclavable (134°C), rail mount Antibacterial filters, 25 pieces Suction tip for drainage, 10 pieces Silicone suction hose, 1.5 meters

Required technical characteristic can be fulfilled by only one Manufacturer of suction units so all other Tenderers are excluded from tender. Other suction units existing on the market could offer same functionality.

Considering above, we ask you to update documentation as proposed to allow other Tenderers to compete.

Odgovor br.1

Prihvatljivo je ponuditi aparat sa vakuumom od 0-1000mbar, odnosno 0-100kPa, kompletnim sistemom za montažu: šinskom stegom, crevom od 1.5m i DIN priključkom za vakuum (nemački standard), autoklavabilnom bocom od minimalno 1.5litre, kao i sigurnosnom posudom od 100ml autoklavabilnom na minimalno 121°C.

Answer No. 1

It is acceptable to bid a device with the vacuum level of 0-1000mbar, i.e. 0-100kPa, the complete mounting system: rail clamp, 1.5 m hose and probe DIN (German standard) for vacuum, autoclavable jar of minimum 1.5liter, as well as the safety jar of 100ml or larger which is autoclavable at minimum 121°C.

LOT 1, ID 1.15.6 Vacuum Povered suction Unit Question No.1

In Tender Documentation following technical characteristics are stated:

- 1. Continuous vacuum regulator
- 2. Vacuum level: 0-1000 mbar
- 3. Horizontal rotation of the vacuum gauge from -45° to +45° for a better visibility
- 4. ON/OFF switch-button
- 5. 100 ml or larger safety jar is autoclavable (134°C)
- 6. Complete mounting system: rail clamp, 1.5 m hose and angled remote probe DIN (German Standard)

for vacuum

Accessories for each unit:

- 7. 2 L collection jar, rail mount, 1 pc
- 8. Catheter holder with polycarbonate tube min 40cm and rail clamp, 1pc
- 9. Antibacterial filters, 10 pieces
- 10. Suction tip for drainage, 10 pieces
- 11. Silicone suction hose, autoclavable, 3 meters
- 12. Operation Manual, 1 pc

We kindly ask you to replace these items with following:

Vacuum regulator

Vacuum level: 0-550 mbar ON/OFF switch-button 100 ml or larger safety jar

mounting system - rail clamp, gas supply hose(central gas connection DIN) for vacuum

Accessories for each unit:

2 L collection jar or set of 2 collection jars 1L (graduated to 0,7L) autoclavable (134°C), rail mount
Antibacterial filters, 10
pieces Suction tip for
drainage, 10 pieces
Silicone suction hose,
1.5 meters

Required technical characteristic can be fulfilled by only one Manufacturer of suction units so all other Tenderers are excluded from tender. Other suction units existing on the market could offer same functionality.

Considering above, we ask you to update documentation as proposed to allow other Tenderers to compete.

Odgovor br.1

Naručilac ostaje pri zahtevanim tehničkim karakteristikama budući da na tržištu postoje više od jednog proizvođača koji može ponuditi predmetna sredstva.

Answer No. 1

The orderer remains by the requested technical features since there is more than one manufacturer in the market producing the subject goods.

LOT 1, ID 1.15.1 Mobile aspirator for suction of the respiratory tract secretion (electric and battery operated)

Question No.1

In Tender Documentation following technical characteristics are stated:

- 1. Flow rate: not less than 35 liters/min
- 2. Vacuum -0.8 bar
- 3. Power supply from grid 220V, from 12V DC car power charge and from the integrated 12V battery
- 4. Continuous operation
- 5. Appliance weight maximum 5kg

Standard accessories:

- 6. polycarbonate autoclavable 1liter bottle,
- 7. anti-bacterial filter,
- 8. set of silicone tubes,
- 9. Suction catheter and conical connector.

We kindly ask you to replace these items with following:

Flow rate: not less than 35 liters/min

Vacuum -0.8 bar or better

Aspirator is electrical or ejector driven (air or O2), from central gas supply or cylinder

Appliance weight maximum 5kg

Standard accessories:

at least one autoclavable bottle, 07, liter or larger

anti-bacterial filter,

set of silicone tubes,

conical connector.

Considering above, The purchaser would provide better competition and allow other bidders to submit acceptable offer for subject equipment.

LOT 1, ID 1.15.2 Mobile aspirator for suction (electric with 2 bottles of 2l, for ICU)

Question. 1.

In Tender Documentation following technical characteristics are stated:

- 1. Suction unit on a mobile stand
- 2. Flow rate: not less than 40 liters/minute
- 3. Vacuum -0.8 bar
- 4. Grid power supply 220V
- 5. Continuous operation
- 6. Appliance weight maximum 7kg
- 7. Standard accessories:
- 8. two polycarbonate autoclavable bottles of 2 liters each,
- 9. anti-bacterial filter,
- 10. set of silicone tubes,
- 11. suction catheter and conical connector

We kindly ask you to replace these items with following:

Suction unit on a mobile stand

Flow rate: not less than 40 liters/minute

Vacuum -0.8 bar or better

Aspirator is electrical or ejector driven (air or O2), from central gas supply or cylinder

Standard accessories:

two autoclavable bottles of 0,7 liters each,

anti-bacterial filter,

set of silicone tubes,

conical connector

Required technical characteristic can be fulfilled by only one Manufacturer of suction units so all other Tenderers are excluded from tender. Other suction units existing on the market could offer same functionality.

Considering above, we ask you to update documentation as proposed to allow other Tenderers to compete.

LOT 1, ID 1.15.3 Stationary, electric aspirator for suction of the respiratory tract secretion

In Tender Documentation following technical characteristics are stated:

- 1. Flow rate: not less than 40 liters/minute
- 2. Vacuum -0.8 bar
- 3. Grid power supply: 220V
- 4. Appliance weight maximum 4kg

Standard accessories:

- 5. polycarbonate autoclavable 1liter bottle,
- 6. anti-bacterial filter,
- 7. set of silicone tubes,
- 8. suction catheter and conical connector

We kindly ask you to replace these items with following:

Flow rate: not less than 40 liters/minute

Vacuum -0.8 bar

Aspirator is electrical or ejector driven (air or O2), from central gas supply or cylinder Appliance weight maximum 4kg

Standard accessories:

at least one autoclavable 1liter bottle,

anti-bacterial filter,

set of silicone tubes,

conical connector

Required technical characteristic can be fulfilled by only one Manufacturer of suction units so all other Tenderers are excluded from tender. Other suction units existing on the market could offer same functionality.

LOT 1, ID 1.15.3 Stationary, electric aspirator for suction of the respiratory tract secretion

Ouestion 1:

In Tender Documentation following technical characteristics are stated:

- 1. Flow rate: not less than 40 liters/minute
- 2. Vacuum -0.8 bar
- 3. Grid power supply: 220V
- 4. Appliance weight maximum 4kg

Standard accessories:

5. polycarbonate autoclavable 1liter bottle,

6. anti-bacterial filter,

7. set of silicone tubes.

8. suction catheter and conical connector

We kindly ask you to replace these items with following:

Flow rate: not less than 40 liters/minute

Vacuum -0.8 bar

Aspirator is electrical or ejector driven (air or O2), from central gas supply or cylinder

Appliance weight maximum 4kg

Standard accessories:

at least one autoclavable 1liter bottle,

anti-bacterial filter,

Required technical characteristic can be fulfilled by only one Manufacturer of suction units so all other Tenderers are excluded from tender. There are models of aspirators on the market that offer the same functionality and we ask you to modify the documentation in accordance with the proposed, to enable others bidders to participate in the procurement of equipment.

LOT 1, ID 1.15.1, ID 1.15.2, ID 1.15.3

Answer.no 1

The orderer remains by the requested technical features since the potential bidder suggests the procurement of aspirators which are powered completely different from what is requested. Ejection driven aspirators and the aspirators powered by gasses from the central power supply system are included in separate positions.

As for the capacity of the aspiration bottles, the Purchaser formed the procurement according to Beneficiary's real needs based on the clinical practice. Therefore, it is not acceptable to bid bottles with smaller volume than specified.

Odgovor br.1

Naručilac ostaje pri zahtevanim tehničkim karakteristikama budući da potencijalni ponuđač sugeriše nabavku aspiratora sa pogonom potpuno drugačijeg tipa od zahtevanog. Aspiratori na elektronskom principu i aspiratori sa pogonom pomoću gasova centralnog sistema obuhvaćeni su zasebnim pozicijama.

Što se tiče kapaciteta aspiracionih boca naručilac je oblikovao nabavku prema svojim realnim potrebama utemeljenih na kliničkoj praksi i nije prihvatljivo nuditi boce manje litraže od navedenih.

LOT 1, ID 1.22 Medical Air Plant

Question no.1

Considering that it is a system for the production of medical air and that such system is considered as medical product and must be registered in the Agency for Medicines and Medical Devices (ALIMS), we consider it is necessary that offered good must be registered with ALIMS. We kindly ask you to add this requirement to the technical specificiation.

Answer 1:

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.

According to our information systems with two compress units are not subject of registration with ALIMS.