

**Procurement of Medical Devices for the Obstetrics and Gynaecology Clinic
“Višegradska” - Clinical Centre of Serbia**

IOP/18-2018/RD

Clarification 2

Issued on September 6, 2018

Question 1

On pages 57 and 58 it says: ""The equipment offered should be manufactured in compliance with Quality Standard ISO 9001 certification for Manufacturer(s) and Service company. Is it allowed to submit ISO 13485 instead ISO 9001?"

Answer 1

Yes, ISO13485 is acceptable.

Question 2

"Since the LOT 2 includes many auxiliary medical devices for which there are no spare parts, such as:

- 2.3.1 I.V. STAND with 2 hooks
- 2.3.2 I.V. STAND with 4 hooks
- 2.3.3 Double bowl stand
- 2.3.4 Bowl stand for heating of physiological saline solutions
- 2.3.5 Kidney bowl
- 2.3.6 Surgical pincers
- 2.3.7 Round sterilizing drum 1
- 2.3.8 Round sterilizing drum 2
- 2.3.9 Round sterilizing drum 3
- 2.3.10 Smooth box with handle 1
- 2.3.11 Smooth box with handle 2
- 2.3.12 Smooth box with handle 3
- 2.3.13 UV lamp
- 2.3.14 Soiled linen trolley
- 2.3.15 Double laundry bag-holder trolley for the sorting

- 2.4.1 Ward screen
- 2.4.3 Cabinet for drugs
- 2.4.4 Wardrobes
- 2.4.5 Swivel stool
- 2.4.6 Swivel stool with backrest
- 2.4.7 Seat trolley
- 2.4.8 Mounting step 1
- 2.4.9 Mounting step 2
- 2.4.10 Swivel stool without backrest
- 2.7.2 Table for premedication for anesthetic 1
- 2.7.3 Table for premedication for anesthetic 2
- 2.7.4 Trolley for intensive care
- 2.7.7 Treatment trolley with accessories
- 2.7.8 Anaesthesia trolley with accessories
- 2.7.9 Peridural trolley
- 2.7.10 Anaesthesia table (CVK, spinal)
- 2.7.11 Table of INOX for anesthesia accessories
- 2.7.12 Service trolley for instruments

Please confirm that it is not necessary to submit for them the spare-parts price list, the manufacturer's statement to provide the spare parts during the warranty period and afterwards, and the service certificate for the engineers.

Answer 2

It is not necessary to submit stated documents for these goods.

Question 3

With reference to the Personnel Capability (page 36) the bidder shall provide minimum 5 (five) suitably qualified employed personnel working in fields related to subject of this contract. We plan to act as a joint venture. Could you please clarify if each member/party of the joint venture should provide minimum 5 employed personnel or 5 in total from all of the parties is sufficient.

Answer 3

This provision does not apply to each member of the joint venture individually, it is sufficient to have 5 employees in total.

Question 4

The Technical Document for Lot 2 Auxiliary hospital and medical equipment for ID 2.4.4 - Wardrobes requests the wardrobe dimensions to be 90x180cm. Wardrobe manufacturers noted to us that the requested dimensions are non-standard for 2-wing wardrobes. Since the standard dimensions for 2-wing wardrobes are 80x180cm, please confirm that it is acceptable also to bid and deliver 2-wing wardrobes in standard dimensions, i.e. 80x180cm

Answer 4

It is acceptable to offer wardrobe with dimensions 80x180cm.

Question 5

"The tendering documents request submission of the ISO 9001 certificate for all manufacturers whose products are being tendered. Within the Lot 2 Auxiliary hospital and medical equipment / Lot 2 Technical Specification Requested ID: 2.1.3 Pillows, 2.1.4 Bedding set, 2.4.4 Wardrobes, 2.3.13 UV Lamp

we plan to bid the products of domestic manufacturers. Since those products are considered non-medical devices, please confirm that it is not mandatory to submit the ISO 9001 certificate for the manufacturer. We hereby note that the domestic manufacturers of the above non-medical equipment do not hold ISO 9001 certificate, but they do hold quality certificates that relate to the products themselves.

Answer 5

It is not mandatory to submit stated document for these goods.

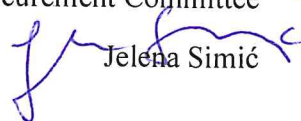
Question 6

Considering the fact that LOT 7 - Furniture and IT contains furniture and as documentary evidence for Technical capacity, Bidders are required to submit Manufacturer's Sales Authorization (for Bidder) and Manufacturer's After Sales Authorization (for Service Company registered in the Republic of Serbia), please confirm that the Bidder is obliged to submit Authorizations only for IT equipment (LOT 7, ID 7.1 - 7.5) because furniture manufacturers do not issue such documents.

Answer 6

It is not necessary to submit Manufacturer's Sales Authorization and Manufacturer's After Sales Authorization for this part of the lot (Furniture)

Public Procurement Committee


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