# Procurement of Medical Devices for Clinical Centre Dr Dragiša Mišović IOP/6-2017/RD

# Clarification no.5

Issued on 19.09.2017.

#### **Question 1:**

On page 27. of Tender documents, paragraph ITB 14.6 says:

"Custom duties on import and other related costs are specially declared."

Concerning that custom duties on import and other related costs will be known only in time of import, and Purchaser did not leave room for such calculations in tender documents, we think that it would greatly ease the tender documents filling for potential bidders if this request would be deleted, for the goods that are not imported at the moment of bid submission. The bidder would confirm that with official statement.

#### Answer 1:

Bid Price should be quoted as DAP, so it is not required to declare import and other related costs. Bids will be evaluated applying the Tender evaluation criterion on the basis of the Tender price quoted as DAP.

# Question 2:

On page 27 of Tender documents, paragraph ITB 18.3 sys:

"Period of time the Goods are expected to be functioning (for the purpose of spare parts): 7 (seven) year"

Also on page 58 it says:

"7. Spare Parts & Accessories & Consumables

7.1 The successful Suppliers will be required to make arrangements in order to guarantee availability of the spare parts during the warranty period and during seven (7) years after the delivery."

Should potential bidders submit confirmation of spare parts availability for seven (7) years? Is it sufficient to submit Bidder's statement as confirmation of spare parts availability?

#### Answer 2:

By signing and submitting bid, the Bidder accepts all requirements specified by tender documentation, including the requirements concerning the availability of the spare parts during the period for seven years.

It is not necessary to submit Bidder's statement as confirmation of spare parts availability.

#### Question 3:

On page 56 of Tender documents, it says:

"Manufacturers' technical literature should be submitted for each item offered and suppliers shall provide necessary documentation (catalogues, guides, brochures, manuals, booklets, etc.) with detailed technical specifications of all items being offered thus enabling the Purchaser to verify the information provided in the offer."

As some of technical characteristics of the goods listed in technical specifications are not explicitly stated in technical literature, is it allowed to submit Manufacturer's statement as proof of technical characteristics?

#### Answer 3:

It is allowed to submit Manufacturer's statement with precise listing of technical characteristics as a proof of technical characteristics of the goods that are not stated in technical literature.

#### Question 4:

On pages 56 and 57 of Tender documents, it says:

2.1. "The equipment offered should be manufactured in compliance with Quality Standard ISO 9001 certification for Manufacturer(s) and Service company.

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"Certificates:

ISO 9001 certification (Quality Management System)

It refers to all manufacturers

Submit copies of certificates"

As the subject of this Public Procurement is medical equipment, is it allowed to submit ISO 13485 instead of ISO 9001?

Majority of renowned medical equipment manufacturers maintain Quality Management System complying with ISO 13485. ISO 13485 was designed on basis of ISO 9001, but specifically for the product scope of medical devices and is even more restrictive.

# Answer 4:

It is allowed to submit ISO 13485 instead of ISO 9001.

#### Question 5:

In technical specifications (excel files) there are some irregularities with numbering:

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LOT 1, position 1.1 — there is no ID 43

— there are 2 (two) IDs 52

LOT 1, position 1.2 — there are no IDs 14, 15, 16

LOT 1, position 1.22 — there are no IDs 14, 45

LOT 2, position 2.1.1 — there is no ID 8
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LOT 3, position 3.4.9 – there are no IDs 13, 18, 25

LOT 3, position 3.4.15 - there are no IDs 13, 18, 25, 34

Please make the necessary changes to numbering, as potential bidders could adequately mark technical literature.

#### Answer 5:

The numbering remains the same to avoid further confusion. There is no missing items in the technical specifications.

# **Question 6:**

1) In technical specification for the LOT 4 – Auxiliary surgical devices ID 4.1. is described generator with basic equipment and consumables. Does this procurement include purchase of generator with basic equipment only or also with consumables, because the name of LOT 4 ID 4.1. is just Auxiliary surgical devices?

#### Answer 6:

Procurement includes Generator with basic equipment only. In that sense, Clarification is given through the AMENDMENT No. 1 of the tender documentation.

## **Question 7:**

2) Can we provide all evidence for the fulfilment of requested conditions, as follows: Labour contracts, work booklets, list of reference, copies of invoices, purchaser statements etc., in Serbian language because we are bidder from the purchaser's country, Serbia?

## Answer 7:

Yes, abovementioned document can be in Serbian.

## **Question 8:**

Is it possible to submit one administrative envelope, even if we are bidding for multiple lots?

#### Answer 8:

It is not possible to submit one administrative envelope for multiple lots.

The bidders shall submit their offers in separate envelopes for each lot

## **Ouestion 9:**

Is it possible to make a discount in case multiple lots are awarded? In fact, the bidding data sheet(BDS)p.25 to 30 of the specifications there is mo ITB Sub-clause 14.4 which must specify wheather it is possible to make a discount if multiple lots are awarded?

Answer 9: Making discount is not possible in this Tender.

# **Question 10:**

Regarding the Section VII. General Conditions of Contract, Section 5 - Language that states the fact that the language of the bid is: English or Serbian, please take into consideration that being an International Competitive Bidding (ICB), accepting Serbian as an alternative language for the bid introduces an unfair advantage to some tenderers, considering the fact that non-Serbian speaking tenderers have to translate the documents from Serbian.

Considering the above mentioned and the fact that the tender dossier was published in English please take into consideration that all the public documents available to all tenderers to be issued in English including the already posted clarifications responses.

Answer 10: All clarifications will be issued in English.

Public Procureme	ent Commison
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