**Procurement of Medical Devices for the for the Institute for Cardiovascular Diseases „Dedinje“**

**IOP/21-2018/RD**

**Issued on October 30, 2018**

Question 1:

On the page 36 of tender documentation under Financial Capability requirements, the Purchaser request a certificate from the competent institution that Bidder didn’t have any registered blockage of their account from the beginning of the 2017 year.

Since these data are publicly available, is it possible for Bidders from the Republic of Serbia to submit an excerpt from official webpage of NBS where that data on account blockage is available for the period of past 3 years?

Answer 1

It is acceptable.

Question 2

On the pages 55 and 56 of tender documentation, it says:  ''2.2. The equipment offered should be manufactured in compliance with Quality Standard ISO 9001 certification for Manufacturer(s) and Service company.''

Majority of renewed medical equipment manufactured 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 as even more restrictive. Is it allowed to submit ISO 13485 instead of ISO 9001?

Answer 2

It is acceptable.

Question 3:

We kindly ask you for confirmation of whether the documents such as catalogs, brochures, instruction for use, manufacturer's statement as a proof of technical characteristics can be submitted as copies and extracts or do we need to submit the original documents?

Answer 3

The purchaser will accept the copies of these documents.

Question 4

Considering that  ID 1.3. Application software packages for ''pace mapping'', automatic CT segmentation and interpretation of tachycardia is a softer product for which there is no service or maintenance, please confirm us that for ID 1.3. we don't need to submit following documentation: After Sales Authorization, Certificate for Servicer, ISO for service company, Manufacturer's Statement of  a satisfactory level of spare parts/accessories/consumables during  seven (7) years after delivery.

Answer 4

We confirm that is not necessary to submit these documents for id 1,3.

Question 5

Please confirm that a JV agreement drawn up in Serbian does not have to be translated into English and in accordance with ITB 10.1

Answer 5

We confirm that it is not necessary to translate JV agreement into English.

Question 6

You are kindly requested to inform us if this project is exempted from VAT and in regard to it confirm that the successful bidder as well as each participant in joint venture (if the contract is awarded to the joint venture) will be provided with a VAT exemption certificates when applicable.

Answer 6

The project is exempted from VAT and each participant in JV will be provided with VAT exemption documentation.

Question 7

In case of the joint venture (JV) please confirm that the Purchaser will accept bank guarantees, payment documents (pro forma invoices, invoices for advance and final invoices) provide by each participant in the JV in the proportion with the value of its participation in the joint bid, i.e. in proportion with the amount of their own bid and in accordance to the Joint Bid Agreement.

With reference to the payment please confirm that you agree to transfer funds to the bank accounts indicated of payment documents of each participant of JV

Answer 7

We confirm that it is acceptable for the Purchaser that each participant provide bank guarantees, payment documents (pro forma invoices, invoices for advance and final invoices), also that payment would be transfer to each participant.

Question 8

With reference to the Law of deadlines for settlement of financial liabilities in commercial transactions, does it mean that the Purchaser will make the settlement of the remaining 50% (40%+10%) within a deadline of 45 days.

Answer 8

The remaining 50% (40%+10%) would be transferred in accordance with GCC 15.1

(ii) On receiving: 40 (forty) percent of the Contract Price shall be paid upon on receipt of the Goods.

(iii) Implementation of Related Services: Ten (10) percent of the Contract Price of the Goods shall be paid upon implementation of all related services stipulated, related to proper functioning of goods, such as but not limited - installation, burn testing, training etc. (per item).

Question 9

Since customs duties and other related costs will be calculated and known at the importation we’d be grateful if you could delete a requirement stipulated in ITB 14.6. that customs duties on import and other related costs should be specially declared so the bid price would be quoted on DAP basis.

Answer 9

It is not necessary to declare that customs duties on import and other related costs

Question 10

Please confirm that the Bidder is not required to submit a statement of spare parts availability for the periods (warranty and 7 years) specified on page 58 , (7. Spare Parts & Accessories & Consumables. Bidder already accepts all requirements specified by tender documentation including the availability of spare parts and accessories by signing and submitting the bid.

In regard to Bidder obligations please confirm that no additional statement won’t be required as well  in connection with maintenance, repair spare parts-stocking and warranty obligations as it will be accepted and confirmed by signing the Manufacturer’s After Sales Authorization form

Answer 10

It is necessary to submit a statement of spare parts availability.

Question 11

Is it acceptable to submit a manufacturer’s statement for those technical characteristics that are not included in the technical literature.

Answer 11

It is acceptable.

Question 12

With reference to the certificate ISO 9001 required for the manufacturer please be informed that ALIMS , among other documents, requires  manufacture’s ISO 9001 and ISO 13485. It means that a valid ALIMS license as a document evidence in this tender already comprise both standards.

In regard to the above please confirm that ISO 9001 is not required for the manufacturer or approve a submission of the certificate ISO 13485 for the manufacturer instead of ISO 9001

Answer 12.

It is acceptable to submit Certificate ISO 13485 for the manufacturer instead of ISO 9001

Question 13

Would you be so kind as to acknowledge the each tendered item that makes an integral part of the main system won’t be required to be provided with the name of the manufacturer as well as the country of origin.

Answer 13

It is not necessary to specify the name of the manufacturer nor the country of origin for parts that are integral part of main system.

Question 14

In case of the joint venture (JV) please confirm that the Purchaser will accept bank guarantees, payment documents (pro forma invoices, invoices for advance and final invoices) provide by  each participant in the JV in the proportion with the value of its participation in the joint bid, i.e. in proportion with the amount of their own bid and in accordance to the Joint Bid Agreement.

With reference to the payment please confirm that you agree to transfer funds to the bank accounts indicated on payment documents of each participant of JV

Answer 14

See Answer 7

Question 15

Please inform us if the Statement of Integrity form is required to be signed by each member of JV separately or the said form has to be signed by the appointed leader of JV only

Answer 15

It is required to submit Statement of Integrity signed by each member of JV separately.