



Belgrade,

CONTRACTING AUTHORITY'S CLARIFICATIONS no. 2

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"Implementation of national screening programme: supply of equipment for colorectal, cervical and breast cancer"

| No | Question | Answer |
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| 1. | <p>LOT 2: CYTOPATHOLOGY LABORATORY EQUIPMENT</p> <p>2.1 Laboratory Light Microscope with Digital Camera</p> <p>2.1.11 Brightness synchronized objectives: 2, 2,5x/0.07, 5x/0.12, 10x/0.25, 20x/0.40, 40x/0.65, 100x1.25 oil</p> <p>Please note that there is no brightness synchronized objectives numbered 2.</p> <p>Please change this specification as below:</p> <p><u>2.1.11 Brightness synchronized objectives: 2,5x/0.07, 5x/0.12, 10x/0.25, 20x/0.40, 40x/0.65, 100x1.25 oil</u></p> | <p>The technical specifications contain a typing mistake. Please read the quoted requirements as:</p> <p><i>"Brightness synchronized objectives: 2,5x/0.07, 5x/0.12, 10x/0.25, 20x/0.40, 40x/0.65, 100x1.25 oil"</i></p> |
| 2. | <p>LOT 2: CYTOPATHOLOGY LABORATORY EQUIPMENT</p> <p>2.1 Laboratory Light Microscope with Digital Camera</p> <p>2.1.13 Digital camera, min. Resolution 7 Mpixel (3072 x 2304)</p> <p>2.1.19 Firewire-IEEE 1394b live image PC connection</p> <p>The above requested specifications are specific to one manufacturer and highly above the intended use of the device.</p> <p>Due to the compatibility with the tender,</p> | <p>Please observe the technical specifications, which include minimum requirements.</p> |

| No | Question | Answer |
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| | <p>please change this specification as below:</p> <p><u>2.1.13 Digital camera, min. Resolution 3.1 Mpixel (2048 X 1536)</u></p> <p>LOT 2: CYTOPATHOLOGY LABORATORY EQUIPMENT</p> <p>2.1 Laboratory Light Microscope with Digital Camera</p> <p>2.1.19 USB 3.0 live image PC connection</p> | |
| 3. | <p>With reference to the tender EuropeAid/135215/DH/SUP/R, please provide us with the banking information as requested below by our bank for the purpose of issuing the tender guarantee:</p> <p>Bank Name:</p> <p>Bank Address:</p> <p>Account Number of the Beneficiary (Delegation of the EU in Serbia):</p> <p>SWIFT:</p> | <p>No such information is to be included in the Tender Guarantee, according to the template published with the Tender Dossier. Please note that the template of the Tender Guarantee and the instructions contained in it should strictly be followed by the issuing institution.</p> |
| 4. | <p>ITEM. 2.1, 2.2 and 2.3</p> <p>The requirement of 100.000 hr lifetime for the LED light is surely a mistake. Please adjust it to 10.000 hr, which is the common standard for such kind of technology?</p> | <p>This is a typing error. Please read the requirement, valid for items 2.1, 2.2 and 2.3, as:</p> <p><i>"Light microscope with long-life LED illumination (10,000h)"</i></p> |
| 5. | <p>ITEM 2.5</p> <p>Specifications indicated "linear autostainer". Is it acceptable a "carousel autostainer" having the same performances?</p> | <p>Please observe the technical specifications, which include minimum requirements.</p> |
| 6. | <p>We find for Light source specified output of 300 W and emergency halogen lamp requirement technically unjustified considering the implemented design and technology of our equipment.</p> <p>We have never received claim on the quality or reliability of the light delivered by our 100 W light source. On the contrary, we registered observations on to high light intensity and color deformation delivered by</p> | <p>Please observe the technical specifications, which include minimum requirements.</p> |

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| No | Question | Answer |
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| | <p>300 W units and also learned that the used starting output, even in surgery, is 15%. As for our 100W unit, default setting for routine examinations is 40%.</p> <p>We would also like to remind that the intended purpose of the equipment is colono-screening procedure, in other words routine diagnostic which means that emergency cases are not going to be treated, (although as explained in our attached letter, lamp failure during the examination cannot occur).</p> <p>The other important issue is Color LCD monitor resolution specified at 1920x1200. Here we would like to point out that the specified resolution cannot be achieved due to the fact that the resolution of the camera processor is 1920x1080.</p> <p>Based upon above quoted facts, we kindly ask you to inform us if our Light source with 100W output without halogen emergency lamp, and Color LCD monitor with 1920x1080 can meet the requirements and purpose of this tender.</p> | |
| 7. | <p>Lot 2, Item 2.1 , 2.2 and 2.3, Laboratory light microscope - Requested feature is „Light microscope with long-life LED illumination (100000h). Could you please check if this LED lamp life is shorter (10.000 hours) - maybe this is printing error.</p> | <p>Please refer to the answer to question no. 4 above.</p> |
| 8. | <p>Lot 2, Item 2.1, 2.2 and 2.3 Laboratory light microscope - Requested feature is „Adjustable torque focusing module ". The modern microscope has high precision focus drive with constant resistant of focus drive. Can we offer microscope with this kind of focus drive?</p> <p>This microscopes fully satisfy routine and research purpose.</p> | <p>Please observe the technical specifications, which include minimum requirements.</p> |
| 9. | <p>Lot 2, item 2.1, 2.2 and 2.3 Laboratory light microscope - Requested feature is „Ceramic coated movable table, right/left hand use, changeable by user". Can you please tell us can we offer: hard coat anodized surface with right drive? From our experience 90% of all</p> | <p>Please observe the technical specifications, which include minimum requirements.</p> |

| No | Question | Answer |
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| | microscopes in Serbia have a mechanical stage with right drive. | |
| 10. | Lot 2, Item 2.1, 2.2 and 2.3 Laboratory light microscope. Requested feature is "Standard condenser, colour coding, 2,5x – 100x". Can you please tell us can we offer standard condenser without colour coding? | No, the requirements of the technical specifications are minimum and have to be met by the offered equipment. |
| 11. | <p>Lot 2, Item 2,1 Laboratory light microscope. Requested features for digital camera are:</p> <p>"Digital camera, min, resolution 7 Mpixel (3072x2304), Live image in full size 2048x1536, min. 12 frames/sec. Pixel size 3.2 x 3.2, Colour filter RGB, Colour depth 30 bit Dynamic range >55dB/600:1, Firewire-IEEE 1394b live image PC connection". Can you tell us can we offer instead requested - the following configuration:</p> <p>"Digital Microscopy Camera 5 Megapixels, color (2560 (H) x 1920 (V))</p> <p>Live frame rate (depending on hardware and software configuration):</p> <p>H x V Frame Rate, 800 x 600 max. 13</p> <p>Pixel size: 2.2 µm x 2.2 µm. Digitization: 3x8 bit/pixel</p> <p>Interfaces: 1 x SD card slot, 1x mini USB 2.0, 1x AV (S-Video), 1x DVI- D (HDMI)"</p> | Please refer to the answer to question no. 2 above. |
| 12. | If the supporting documents are not written in one of the official languages of the European Union, a translation into the language of the call for tender must be attached. Is it required to have translation certified by official interpreter? | No, a certified translation is not required. |
| 13. | <p>All tenders must be submitted in one original, marked 'original', and three copies signed in the same way as the original and marked 'copy'.</p> <p>Does three copies must include technical documentary proofs (catalogues, brochures, prospects etc.) in copies or original?</p> | Both the original offer and the three copies may include copies of the technical documentation ("technical documentary proof"), providing information about the technical specifications of the offered supplies. Originals are not mandatory. |

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| No | Question | Answer |
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| 14. | Training is required as a part of technical and financial offer. Which education level is required (doctors or nurses, or both), where (locally or in EU reference centre) and in which period? | Training is required for nurses locally for a period of 7 days or individually when installing equipment. |
| 15. | <p>Catalogues, brochures, booklets are required to provide information about technical specification of supplies. Original required or copies are sufficient?</p> <p>In case particular technical characteristic is not presented in catalogues, brochures and booklets, is it acceptable to submit original manufacturer's statement where is declared that supplies comply with required technical characteristic?</p> | <p>Please refer to the answer to question no. 13 above.</p> <p>Manufacturer's statement of compliance with certain technical requirement is equivalent to the manufacturer's technical documentation (brochures, datasheets etc).</p> |
| 16. | <p>The Contractor shall insure the goods for their replacement value (110%) during delivery and commissioning.</p> <p>Please explain why is asked for 110% value of goods?</p> | It is the standard policy of the Contracting Authority to ask for such level of insurance. |
| 17. | What is acceptable documentary proof for manufacturer's commercial warranty and which details are required to be described? | It is up to the Tenderer to provide satisfactory documentary evidence of and description of the organisation of the (manufacturer's) commercial warranty to prove compliance with the requirements in the Tender Dossier. |
| 18. | Is "DICOM" necessary in system for capturing image and video documentation? Is the documentation solution required for pictures and videos? | DICOM is required for image and video documenting. |
| 19. | Is real-time display of living image - touch screen (LCD-TFT 17") absolutely needed? If yes, is it possible to offer smaller dimension than 17"? | Please note that the requirements of the technical specifications are minimum and have to be met by the offered equipment. |
| 20. | <p>Lot 3. Item 3.1</p> <p>Please confirm that offered desktop computers have to be compliant with Energy Star 5.2 and EPEAT.</p> | <p>According to the technical specifications for item 3.1, the offered equipment has to be compliant with the following standards: CE and/or TÜV GS, RoHS, EPEAT/WEEE, Energy Star.</p> <p>Moreover, according to section "Mandatory Requirements for Lot 3" of Annex II+III: Technical Specifications and Technical</p> |

| No | Question | Answer |
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| | | <p>Offer, "All equipments should, furthermore, comply with the state of the art features concerning safe operation, energy saving and environ-mental safety, in line with the generic policies or the practical measures in use within the EU, namely within the scope of Product Safety, Energy Efficiency and Environment Management, as applying; tenderers are thus requested to state in their offers how do they address such issues by means of appropriate manufacturing or operational characteristics or instructions".</p> |
| <p>21.</p> | <p>Lot 3. Item 3.1</p> <p>Please confirm that you need proof from the Energy Star and EPEAT internet sites.</p> | <p>According to the technical specifications for item 3.1, the offered equipment has to be compliant with the following standards: CE and/or TÜV GS, RoHS, EPEAT/WEEE, Energy Star. At the time of tender, the certificates (or other means) proving compliance with these standars have to be included in the offer.</p> |
| <p>22.</p> | <p>Technical specifications + technical offer) for lot 2, section "Standards", page 3., it is stated:</p> <p>"Tenderers shall ensure conformity of the equipment with all applicable Serbian (Medicines and Medical Devices Agency) and EU technical regulations".</p> <p>Does it mean that we must submit in our tender offer copies of registration certificates for offered items issued by Medicines and Medical Devices Agency of Serbia or is it enough to submit our signed statement that we shall, under penalty of perjury, ensure conformity of the equipment with all applicable Serbian (Medicines and Medical Devices Agency) and EU technical regulations?</p> | <p>As specified in the answer to question no. 1 in the Contracting Authority's Clarifications no. 1, copies of registration certificates or similar documents for the offered equipment issued by Medicines and Medical Devices Agency of Serbia do not have to be included in the offer.</p> <p>Tenderers must be aware that in order to finalise the equipment's import procedures, at the time of contract implementation, they shall have to obtain the certification of the goods by the Medicines and Medical Devices Agency of Serbia.</p> <p>To that effect, the Tenderers shall state in their offers that the equipment will comply with this requirement at the time of delivery/contract implementation, if this is the case.</p> |
| <p>23.</p> | <p>LOT no.1</p> <p>Is the Insertion Tube outer diam. of 13.2mm acceptable?</p> <p>Explanation:</p> <p>Speaking of different producers there is minimal diference in the diameter of</p> | <p>According to the technical specifications the insertion tube's outer diameter should be less than 13 mm.</p> |

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| | <p>insertion tube that does not significantly reflect to the equipment functionality and quality. The quantity over 30 video colonoscopes with the Insertion Tube outer diameter 13.2mm, produced by YYY, was installed in the hospitals on the territory of Serbia, including clinical centres, health institutes and general hospitals using this equipment for years.</p> <p>Therefore, we suggest this technical characteristic to be stated as following:</p> <p>Insertion tube outer diam.: < 13,2mm</p> | |
| <p>24.</p> | <p>LOT no.1</p> <p>Is it acceptable to have the Light Source and the Video System unit integrated in one unit?</p> <p>Explanation:</p> <p>At different producers there are the light source and the video processor as the separate units existing or as those both integrated in one unit. In the sense of functionality and quality of the equipment to be offered, there is absolutely no any difference between these two options. One of the worldwide reputable producers of endoscopy equipment, XXX, all its video processors produces with the light source integrated in it. On the territory of Serbia there are more than 40 video systems installed. Therefore, we suggest this technical characteristic to be stated as following:</p> <p>Light Source quantity: 10 (ten) or integrated in the Video System unit.</p> | <p>As long as the requirements of the technical specifications are met, Light Source integrated into the Video System Unit may be considered. However, please note that in line with section 4.3.4 of the Practical Guide the Contracting Authority cannot provide a prior opinion on the assessment of an offer, such assessment being the duty of the Evaluation Committee.</p> |
| <p>25.</p> | <p>LOT no.1</p> <p>Is it acceptable the Emergency lamp to be LED lamp instead of the halogen lamp only?</p> <p>Explanation:</p> <p>The emergency lamp (incorporated in the light source) exist in the equipment produced by each producer of endoscopy equipment, whether it is LED or halogen. The LED</p> | <p>Please observe the technical specifications, which include minimum requirements.</p> |

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| | <p>lamps are the products of more recent technology. On the territory of Serbia there are more than 40 YYY video processors with the LED emergency lamp integrated in.</p> <p>Therefore, we suggest this technical characteristic to be stated as following:</p> <p>Emergency Halogen or LED lamp.</p> | |
| 26. | <p>LOT no.1</p> <p>Is it acceptable the USB storage to be instead of the memory card?</p> <p>Explanation:</p> <p>The function of recording and archiving the images in the memory card or in the USB is completely the same, it differs only the physical media,</p> <p>Therefore, we suggest this technical characteristic to be stated as following:</p> <p>Memory Card or USB storage</p> | <p>Memory card and USB memory stick storage are considered equivalent.</p> |
| 27. | <p>LOT no.1</p> <p>Is it acceptable the Resolution of Colour LCD Monitor to be 1920x1080 (FHD)?</p> <p>Explanation:</p> <p>FHD (full HD) resolution is the generally accepted standard and it is used at Aspect ratio 16:9, unlike WUXGA resolution that is used at the monitors with Aspect ratio 16:10. In the sense of functionality there is no any difference in the image itself.</p> <p>Therefore, we suggest this technical characteristic to be stated as following:</p> <p>Resolution: 1920x1200 (WUXGA) or 1920x1080 (FHD)</p> | <p>Please observe the technical specifications, which include minimum requirements.</p> |
| 28. | <p>In ANNEX II + III: TECHNICAL SPECIFICATIONS + TECHNICAL OFFER, Item Number 1.1 Video Colonoscope system, for Video Colonoscope, line "Depth of view: 3-100 mm", please give us your reply:</p> | <p>Please note that the requirements in the technical specifications are minimum. Offers meeting or exceeding these requirements are considered acceptable.</p> |

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| No | Question | Answer |
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| | <p>- is it acceptable to offer depth of field: 2-100 mm, due to the fact that this gives better possibilities for medical procedure?</p> | |
| 29. | <p>In ANNEX II + III: TECHNICAL SPECIFICATIONS + TECHNICAL OFFER, Item Number 1.1 Video Colonoscope system, for Light source, line "300W Xenon lamp, 500 hrs. life time", please answer:</p> <p>- is it acceptable to offer Light source with LED light? LED light is the latest technology being used in advanced light devices. LED light consumes less energy than a xenon lamp, also, it has much more longer lifetime. Expected life time for LED lamp is more than 5000 hrs., which is almost no lamp replacement. This minimizes lamp replacement, while reducing energy and noise.</p> | <p>Please observe the technical specifications, which include minimum requirements.</p> |
| 30. | <p>In ANNEX II + III: TECHNICAL SPECIFICATIONS + TECHNICAL OFFER, Item Number 1.1 Video Colonoscope system, for Light source, line "Emergency halogen lamp", please answer:</p> <p>- is it acceptable to offer Light source with LED light which has two LEDs inside the processor? In the unlikely event of breakdown of one LED, it is possible to use the other LED lamp for withdrawal of the endoscope.</p> | <p>Please refer to the answers to questions no. 25 and 29 above.</p> |
| 31. | <p>In ANNEX II + III: TECHNICAL SPECIFICATIONS + TECHNICAL OFFER, Item Number 1.1 Video Colonoscope system, for Video system unit, line "Memory card storage", please reply:</p> <p>- is it acceptable to offer portable memory storage by USB connection? This kind of connection is the most common today, also well accepted.</p> | <p>Please refer to the answer to question no. 26 above.</p> |
| 32. | <p>In ANNEX II + III: TECHNICAL SPECIFICATIONS + TECHNICAL OFFER, Item Number 1.1 Video Colonoscope system, there are technical specifications for Light source and Video system unit. We ask:</p> | <p>Please refer to the answer to question no. 24 above.</p> |

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| | <p>- is it acceptable to offer Light source and Video Processor together as one item solution, not separated in two items?</p> | |
| 33. | <p>In ANNEX II + III: TECHNICAL SPECIFICATIONS + TECHNICAL OFFER, it is written: "All items supplied in this lot shall include full manufacturer's commercial warranty granted for a minimum of two years from provisional acceptance."</p> <p>Special Conditions, Article 32, Warranty obligations, the following is written: "32.7 The warranty must remain valid for one year after provisional acceptance."</p> <p>- Please explain which warranty will be acceptable, one valid 12 months or the one valid for two years after provisional acceptance?</p> | <p>Please note that the quoted paragraphs from the Tender Dossier refer to two types of warranty:</p> <p>The contractual warranty - the warranty of the Contractor that the supplies are new, unused, without defects, of the most recent models and incorporate all recent improvements in design and materials. This warranty must remain valid for 1 year after provisional acceptance (article 32 of the General Conditions, article 32.7 of the Special Conditions and section "Warranty" of Annex II+III: Technical Specifications + Technical Offer);</p> <p>The manufacturer's commercial warranty - the warranty the manufacturer provides for a defined period that the supply will be free from structural defects due to substandard material or workmanship, under conditions of normal commercial use and service. The Commercial warranty should not be confused with - and might go beyond - the warranty period of the contract (article 32.6 of the Special Conditions and section "Commercial Warranty" of Annex II+III: Technical Specifications + Technical Offer).</p> <p>Please further consult the "glossary of terms" annexed to the Practical Guide, available online at the following address: http://ec.europa.eu/europeaid/prag/annexes.do?group=A.</p> |
| 34. | <p>Special Conditions, Article 12 Insurance, please, specify which exact type of the insurance is needed.</p> <p>Is it acceptable to have two insurance policies - one covering the goods to its destination at the customs and the other one which would cover local transport and all other local costs?</p> | <p>Please note that Article 12 of the Special Conditions refers to a single insurance policy that shall cover <i>"the risks during shipping and handling, storage, local transport, installation, covering losses due to traffic accidents, transport damage, theft, improper handling, fire, water, lightning, and professional malpractice, from the time of shipment (ex factory/warehouse) until the issuance of the Provisional Acceptance Certificate"</i>.</p> |

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| 35. | Special Conditions, Article 26.5, General principles for payments, could you, please, specify if the pre financing guarantee refers to complete value of the contract (equal or below EUR 300 000) or refers to percentage of 40% of the value? Is the pre financing guarantee needed for contract values above 300.000 EUR? | Please note the wording of the article 26.5, paragraph a), of the Special conditions: " <i>if the pre-financing is requested and is equal or below EUR 300 000 (...)</i> ". The amount quoted refers to the amount of the pre-financing and not to the value of the contract. The need to provide a pre-financing guarantee is linked with the amount of the pre-financing (if requested by the Contractor). |
| 36. | Must the bidder provide official proof that it is registered in the Bidder's Register at the Business Registers Agency? | No such requirement is included in the Tender Dossier. Please note that the provisions of article 3.2 of the Instructions to Tenderers: " <i>These terms refer to all nationals of the above states and to all legal entities, companies or partnerships established in the above states. For the purposes of proving compliance with this rule, <u>tenderers being legal persons, must present the documents required under that country's law(...)</u></i> ", implies that the documents proving the registration of the company, issued by the respective national business register, have to be provided. |