



**EUROPEAN UNION**

DELEGATION TO THE REPUBLIC OF SERBIA

Belgrade, 01/11/2010

**CONTRACTING AUTHORITY'S CLARIFICATIONS No. 1**

**Supply of equipment for the Implementation of the National screening programme for colorectal, cervical and breast cancer**

**Publication ref.: EuropeAid/129567/C/SUP/RS**

**Tender no: 09SER01/05/21**

No	Question	Answer
1.	We're writing to you after reading the call for tender concerning the "Supply of equipment for the Implementation of the National screening programme for colorectal, cervical and breast cancer", published on the Tenders Electronic Daily web-site, in order to ask for a clarification on our possibility to take part in one lot only of the mentioned supply. Should your response be positive, we would request you please to forward us a copy of the LOT. 8 specifications (office and lab furniture).	Yes, you can bid for only one lot.  Tender Documents are available at the following addresses:  <a href="https://webgate.ec.europa.eu/europeaid/online-services/index.cfm?do=publi.welcome&amp;nbPubliList=15&amp;orderby=upd&amp;orderbyad=Desc&amp;searchtype=RS&amp;aofr=129567">https://webgate.ec.europa.eu/europeaid/online-services/index.cfm?do=publi.welcome&amp;nbPubliList=15&amp;orderby=upd&amp;orderbyad=Desc&amp;searchtype=RS&amp;aofr=129567</a>  and  <a href="http://www.europa.rs">www.europa.rs</a>
2.	We would like to bid for Lot 9: FOB Tests for cancer screening programme only. Please can you advise if this is possible and how we should go about this?	See answer n.1.
3.	Do you have additional separate documentation with detailed characteristics about FOBT required, and how to obtain that documentation	No additional separate documentation with more details characteristics than those mentioned in the specifications is available.
4.	When and on what account tender guarantee (1,000 E for lot 9) is to be given?	A tender guarantee amounting to Euro 1,000 must be made out by your financial institution as per template No. 10 "Tender guarantee" in the tender dossier, and has to be included in the tender as per article 11 of the Instructions to tenderers.
5.	Our company is representative of the renowned manufacturer of medical equipment and currently only company that has a certification (Mammographic Type Test) of EUREF (European Reference Organization) (EUREF <a href="http://www.euref.org/">http://www.euref.org/</a> ) Council for Quality Assured Breast Screening and Diagnostic Services, which represents top of pyramid experts in that field.	There is no derogation on the rule of origin for this tender because of the availability of products with EU certificate of origin.  Concerning software please read answer n.7.

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	<p>"Mammographic Type Test" include:  <a href="http://ikrweb.uni-muenster.de/aqs/Richtlinien/qualitaet_mammo/qualitaet_mammo.html">http://ikrweb.uni-muenster.de/aqs/Richtlinien/qualitaet_mammo/qualitaet_mammo.html</a>. The manufacturer is from the United States but the crucial parts are produced in the EU. This equipment is in Serbia already installed on the most important and the highest frequency of patients tertiary health care facilities, where he undoubtedly proved their unmatched quality. Regarding the subject of procurement under this tender, is equipment for implement the National Programme of screening for breast cancer, we believe that it is necessary to get the only one certified by EUREF, a manufacturer of analog and digital mammography units, our company be provided the opportunity to participate in this tender. Does our company as a representative of the manufacturer, and the manufacturer itself meet the requirement of the origin of the equipment as necessary qualifications for participation in this tender?</p> <p>Also refer the request for clarification regarding the conditions for participation: "TERMS OF PARTICIPATION", 1 Eligibility and rules of origin: Participation is open to all legal persons participating either individually or in a grouping (consortium) of tenderers which are established in a Member State of the European Union or in a country or territory of the regions covered and / or Authorised by the specific instruments applicable to the program under which the contract is Financed (see item 22 below). All goods supplied under this contract must originate in one or more of these countries. Participation is also open to international organizations. Participation of natural persons is directly governed by the specific instruments applicable to the program under which the contract is Financed.</p> <p>The required specification for the third lot: ANNEX II III: TECHNICAL SPECIFICATIONS TECHNICAL OFFER, Lot 3, technical specifications, Item number 3.1, workstation The required software for the operating system workstations "Licensed MS Windows XP MS 7 or 6" manufacturers Microsoft, USA.</p>	
6.	<p>Are any of the special operation conditions for the participation of U.S. manufacturers is applied in this case?</p>	<p>There is no derogation on the rule of origin for this tender because of the availability of products with EU certificate of origin.</p> <p>Please refer to Art. 2.3.1 of EU Practical Guide  <a href="http://ec.europa.eu/europeaid/work/procedures/im">http://ec.europa.eu/europeaid/work/procedures/im</a></p>

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No	Question	Answer
		<a href="http://ec.europa.eu/europeaid/work/procedures/implementation/practical_guide/index_en.htm">plementation/practical_guide/index_en.htm</a>
7.	What are the conditions when it comes to eligibility and rules of origin applied in this case and the required software from the U.S.?	<p>An EU certificate of origin to be issued by a relevant authority doesn't take into account only the country of production/manufacture of the product.</p> <p>Some products have no equivalents and are produced only by a single manufacturer.</p>
8.	Do these conditions applied in this case can be applied in case the company Hologic Inc. also from the U.S.? In case these conditions do not apply, we ask for reasons for that and clarification of these reasons.	<p>There is no derogation on the rule of origin for this tender because of the availability of products with EU certificate of origin.</p> <p>Please refer to Art. 2.3.1 of EU Practical Guide <a href="http://ec.europa.eu/europeaid/work/procedures/implementation/practical_guide/index_en.htm">http://ec.europa.eu/europeaid/work/procedures/implementation/practical_guide/index_en.htm</a></p>
9.	<p>Does the software vendors out of the EU Member States may participate in the tender? If vendors of Software outside EU Member States can not participate in this tender, we are asking for clarification of these reasons, taking into account the fact that one of the required software is manufactured in USA?</p> <p>The intention of such a request for clarification is to provide situation for manufacturer of mammography with proven best features and currently the only certified by the EUREF-A, Hologic Inc.. to participate make their offer in order to provide equipment for the implementation of the National Programme for breast cancer screening in Serbia with goal to be appropriate and in accordance with the norms and conditions that are recommended in the European Union.</p>	<p>There is no derogation on the rule of origin for this tender because of the availability of products with EU certificate of origin.</p> <p>Please refer to Art. 2.3.1 of EU Practical Guide <a href="http://ec.europa.eu/europeaid/work/procedures/implementation/practical_guide/index_en.htm">http://ec.europa.eu/europeaid/work/procedures/implementation/practical_guide/index_en.htm</a></p>
10.	<p>As mentioned in LOT 9 there is a requirement for 40 000 FOB Test units which will be used in CRC prevention program in Serbia.</p> <p>As a leading European wide supplier of such FOB test system based on the state of the art quantitative immunochemical analysis of human hemoglobin as a marker of CRC - which is recommended by the report "European Guidelines for Quality Assurance in Colorectal Cancer Screening" of the European Commission, see Chapter 4, the list of suppliers - we would like to raise the following issue and address the question:</p> <p>The system we Supply, support and service is "OC Sensor" produced by Eiken Chemical Industries Ltd in Japan but distributed, supported and serviced European wide by MAST group in Germany, UK and France, and in Serbia by LKB Vertriebs GmbH from</p>	<p>There is no derogation on the rule of origin for this tender because of the availability of products with EU certificate of origin.</p> <p>Please refer to Art. 2.3.1 of EU Practical Guide <a href="http://ec.europa.eu/europeaid/work/procedures/implementation/practical_guide/index_en.htm">http://ec.europa.eu/europeaid/work/procedures/implementation/practical_guide/index_en.htm</a></p>

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	<p>Vienna, Austria. FOB test system we supply is perfect for cancer screening projects and it meets and exceeds all criteria described under your test specifications except the origin of product. Nevertheless OC sensor is recommended by EU Commission ( see report "European Guidelines for Quality Assurance in Colorectal Cancer Screening" of the European Commission, see Chapter 4, the list of suppliers) and it is already accepted as a basis for nationwide screening programs within those EU countries that has established such programs. As a result we have excellent references all over the EU (Scotland, Austria, Netherlands, Germany, Slovenia, Hungary etc.) demonstrating that our test system perfectly fits various CRC screening programs and fulfils the conditions requested in your tender as well.</p> <p>The automated analyzer "OC Sensor" is rapidly measuring and precisely quantifying human hemoglobin level in stool specimens in a highly specific manner and without interferences. System has already been evaluated in many European pilot and screening studies and is the only system passing RCT (randomized controlled trials) studies giving us the lead in scientific proof. Additionally the very stable sampling device, which has been optimized during more than 10 years of development and use, corresponds to UN 3373 standard demonstrating sample stability of 12 days which is far longer than requested in your tender!</p> <p>Therefore, we would kindly ask you to consider granting us derogation from the rule of origin and giving us an opportunity to participate in this tender. This would place Serbia in a position to start an innovative prevention program in accordance to EU Commission recommendations in a proper way and it would make justification of expenditure of EU money given for such a program far simpler.</p>	
11.	<p>Is it possible to ask less than 60% of pre-financing in order this pre-financing not to exceed EUR 150.000? If less than 60% of pre-financing is requested in the offer and in the case that pre-financing does not exceed EUR 150.000, does the Contractor still have to provide a financial guarantee for the full amount of the pre-financing payment?</p>	<p>Yes, it is possible.</p> <p>No pre-financing guarantee is needed for amounts lower than 150,000 EUR.</p>
12.	<p>In TECHNICAL SPECIFICATION for LOT 1 we found request for Mammography dedicated dry Imager. In TECHNICAL SPECIFICATION for LOT 2 we found connectivity request for DIGITAL MAMMOGRAPHY UNITS (Autoprint and DICOM Print (Basic Grayscale Print User)), and for constituent Diagnostic Review Workstation (DICOM Print), but no</p>	<p>Please just bid for the items and quantities requested.</p>

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No	Question	Answer
	Mammography dedicated dry imager. Do Institutes listed in Delivery, installation and training list (pg. 11 of ANEX II + III: TECHNICAL SPECIFICATION + TECHNICAL OFFER for LOT 2 – DIGITAL MAMMOGRAPHY UNITS) already have imagers or we need to offer mammography dedicated dry imagers for LOT 2 as for LOT 1?	
13.	<p>Lot 4: Colonoscope            Lot 5: Colonoscopy Simulator            Item 4.1 : Video Colonoscope :            Item 5.1 : Colonoscope Simulator:</p> <p>According to our market research these items which are specified in technical specifications are not originated in European Union countries. So we kindly request you to give derogation for these items.</p>	There is no derogation on the rule of origin for this tender because of the availability of products with EU certificate of origin.
14.	<p>Document A. Instructions to tenderers, point 3.5. What did you mean by: tenderers must prove that they comply with necessary legal, technical and financial requirements? Is it acceptable to provide only the statement or do you require some additional documents? If you require some additional documents, please state which ones.</p>	<p>Please read article 3.4 and 21.1 of the instructions to tenderers as well as the relevant parts of the PRAG at the following link:</p> <p><a href="http://ec.europa.eu/europeaid/work/procedures/implementation/practical_guide/index_en.htm">http://ec.europa.eu/europeaid/work/procedures/implementation/practical_guide/index_en.htm</a></p>
15.	<p>Document A. Instructions to tenderers, point 24. It is explained in the Cancellation of the tender procedure that one of criteria for cancellation is if all technically compliant tenders exceed the financial resources available. In order not to exceed planned tender value, could you please provide us with financial resources available (evaluated tender value) for LOT 1, 2 and 3?</p>	<p>The purpose of a tender is to collect offers from tenderers and award a contract to the most advantageous technically compliant bidder. Therefore, no budget estimate shall be provided to the bidders at any stage.</p>
16.	<p>Document A. Instructions to tenderers, point 9. It is stipulated that the language of the tender is English, and that all supporting documents should be translated into the language of the call for tenders. Is it obligatory to provide translations verified by an official court translator registered at the Ministry of Justice of Republic of Serbia?</p>	<p>Since the language of this tender is English, all documentation has to be presented in this language. Documentation in other languages should be translated into English. There is no need for an authorised or official translation.</p>
17.	<p>LOT 1 and 3 documents Annex II+III: Technical specifications + Technical offer, page 1, it is requested from Bidder to provide necessary documentation such as catalogues, brochures, booklets that inform of details of technical specifications that sufficiently define the equipments being offered. If all relevant data are not listed in above mentioned documents, is it acceptable to submit Original Statement of producer or offerer's detailed technical proposal, where such system technical features and parameters are stated?</p>	<p>All products characteristics and features requested have to be proved by supporting or technical documents. Declarations of compliance are not sufficient to verify compliance with the technical specifications.</p>

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No	Question	Answer
18.	LOT 1 Analogue Mammography Unit and Integrated CR Unit: in Annex II+III document Technical specifications + Technical offer: Page 5, Generator - It is requested kV range: 22-35 kV. Is it acceptable to offer generator with kv range: 23-35 kV?	Yes, this is acceptable.
19.	Page 6, Automatic exposure control - It is requested solid state detectors. Do you mean AEC solid state detectors? If not, could you please explain what is it related to?	Yes, this relates to AEC solid state detectors.
20.	Page 6, Automatic exposure control - It is requested Location indication with LED display. Is it acceptable that system has min. 6 detectors locations but without LED display for location indication?	Yes, this is acceptable.
21.	Page 6, Gantry - It is requested Rotation: min +180°/-135°. Would you consider as equivalent request Rotation: min. +135°/-180°, due to same range of rotation. It is only up to producer technology, labelling and direction of rotation, but results are the same.	Yes, this shall be considered equivalent.
22.	Page 7, Safety features - It is requested Automatic motorized compression release in case of power loss. Is it acceptable to change it in Automatic motorized or manual compression release in case of power loss?	Yes, this is acceptable.
23.	Page 7, Recording system - It is requested Bucky factor: R=5:1, approx. 36 lines/cm. Does it mean that system with Bucky factor R=5:1 and 31 lines /cm is also acceptable and not eliminatory?	Yes, this is also acceptable.
24.	LOT 3 Mammographic Workstation, Page 6, Workstation - It is requested contrast at least 800:1 for 2x medical computer screen for mammography. Clinical practice has shown that 500:1 contrast is sufficient for mammography purpose. So, is it acceptable to offer contrast 500:1?	Yes, this is acceptable.
25.	Page 8, It is requested Display of several series on the computer screen and Display of several series on several computer screens. Do you consider under this request display of images from series in full resolution on both monitors and their comparing? Otherwise there is no sense to display different series because there is no diagnostic possibility in such way.	Yes, the display of images from series in full resolution on both monitors and their comparison is here requested.
26.	Page 8, The relevant images can be specifically marked (key image marked). What did you mean by this request? Could you please be so kind to explain in more detailed way?	This is a filming tag. It is used for the marking of certain images that can be written to a laser camera.

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27.	Page 9, Could you please clarify and explain following for Magnify / Pan: Extended Monitor Display, Magnify Rectangle, Magnify / Pan reset, Magnify glass: Interactive Magnification, Magnify Glass: 1:1 / not shown Pixels options.	These provisions depict the possibilities of digital image zooming.
28.	LOT 1, 2 and 3: Annex II + III – Technical specifications + Technical offer – Mandatory requirements/ Documents, page 4 for Lots 1, 2 and 3. In mandatory requirements you requested: “The following documents shall be delivered for all equipment – service and operation manuals in English and Serbian language, execution guidance/installation drawings and certificates of compliance to safety norms and standards and/or trial test results at the manufacturer's facility”. Please confirm whether this relates to delivery of these documents along with the equipment, upon the selection of the best bidder and award of the contract.	Yes, this is meant to be handed in only by the winner at the time of delivery or where necessary at the time of pre-shipment inspection.
29.	Question 1 (Articles 7.2 and 21.5 of the Instructions to Tenderers) If the tenderer is awarded with the agreement covering more than one lot, could the tenderer provide the performance guarantee for each lot respectively or is it mandatory to provide one performance guarantee for the entire contract covering more than one lot? In addition, if the provision of the single performance guarantee is mandatory in the case of one contract covering more than one lot, what are the guidelines for the Contracting Authority when deciding whether to conclude one or more contracts with the tenderer awarded with one or more lots?	Yes, the tenderer shall present separate performance guarantee for each lot of the contract also due to the different implementation periods.
30.	Question 2 (Articles 21.1 and 21.2 of the Instructions to Tenderers and Article 2.4.11 of the Practical Guide) Should the documentary proofs confirming the tenderer's eligibility and its capacity under the section 2.3.3 and section 2.4.11 of the Practical Guide be submitted together with the offer, or these documentary proofs are to be provided upon the receipt of notification of award?	What you write is correct. Please see answer n. 14.
31.	Question 3 (Mandatory requirements for Lots 1, 2 and 3 – Warranty): All items supplied in these Lots shall include full manufacturer warranty, granted for minimum of two years. Is it acceptable to provide full tenderers two year warranty instead for the offered systems?	If a tenderer is not the manufacturer of the goods offered, such tenderer has to provide the proof that the manufacturers warranty is valid at least for a period of two years.  If manufacturers warranty is longer than two years it is of course acceptable.
32.	Referring to the public procurement procedure by Ordering Party we expose as follows. Granted that:	Dual-track X-ray tube ensures the lowest possible dose to suit specific breast characteristics,

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No	Question	Answer
	<p>a) These supply contracts are financed by the European Community with European funding program</p> <p>b) Ordering Party is European Union / Delegation to the Republic of Serbia</p> <p>c) This Public procurement is as EC Reg . No 1085/2006 / IPA that strongly promotes the business within the European Community</p> <p>d) As INSTRUCTIONS TO TENDERERS 09 SER 01 05 21 art. 3 / Participation</p> <p>e) As INSTRUCTIONS TO TENDERERS 09 SER 01 05 21 art. 4 / Origin</p> <p>Granted all the above mentioned, specifically referring to the Lot. No. 2 Digital mammography units,</p> <p>It is our opinion that the participation of European manufacturers in this tender is strongly limited, considering, that only two international manufacturers CAN OFFER PRODUCTS EXACTLY CORRESPONDING to the technical characteristics specified in the tender invitation.</p> <p>More precisely two of the technical characteristics specified in the tender invitation are highly restrictive and disputable and they should be amended for the following REASONS</p> <p>- X-ray tube/dual track tubes</p> <p>X ray tube/dual track tubes are a technological heritage of Analog Mammography when the evolution of Digital Mammography makes the actual state of the art in terms of Lower Dose and enhanced image quality based on Tungsten target with Rhodium or silver filtrations.</p> <p>The higher dose released to the patient with Mo target makes a double target tube only more expensive and delicate without any Clinical Benefit.</p> <p>For the above reasons a double target tube can't be identified as qualifying characteristics vs. those units having a single Tungsten target tube.</p> <p>This requirement is obsolete, and penalizes those Manufacturers investing in Technological innovation and taking care of Patients protection minimizing the Dose.</p> <p>It's our opinion that mammography devices can provide highest quality without this feature.</p> <p>Conclusion: also a single target tungsten tube has to be admitted.</p>	<p>especially important for younger women with radiographically dense breasts.</p> <p>Technical requirements specified in Annex II + III for Lot 2: Digital Mammography units are not changed.</p>
33.	<p>Rotation speed: minimum 8500 RPM</p> <p>In analog mammography with Mo tube High Speed Rotation was useful to enhance tube loading reducing exposure time and related possible artefacts due to patient displacement but there is a cost to pay for High Speed Rotation in terms of higher tube assembly</p>	<p>High-speed rotation generally increases the power capacity of a tube by approximately 60%. There are Manufacturers of Mammography units with 10.000 rpm anode rotation rate.</p>

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	<p>thermal loading and life reduction due to higher mechanical stress.</p> <p>Tungsten tubes representing the state of the art for Digital Mammography have two times the loading capabilities of Molybdenum tubes without high Speed Rotation.</p> <p>It's our opinion that this feature is not qualifying and mammography devices can provide high quality without it.</p> <p>Conclusion: Rotation speed minimum 8500 RPM has to be removed</p>	<p>Technical requirements specified in Annex II + III for Lot 2: Digital Mammography units are not changed.</p>
34.	<p>Autoprint</p> <p>One of advantages of Digital Radiology is the possibility is the possibility to eliminate the cost, the pollution and storage related to the images printed on film.</p> <p>Nowadays the X ray report can be done on the base of digital images on 5 Mpixels monitor, in the Dicom world the DicomDir function is provided to supply the study to the patient on a small world and cheap CD Rom and the Hospital can reduce the physical archive space storing all the images by means of the electronic archive of the PACS.</p> <p>For the above mentioned reasons Autoprint function can't be indentified as qualifying characteristics of a state of the art systems that in any case gives the possibility of printing the images if necessary only by means of a simple click.</p> <p>The request for autoprint has to be removed</p>	<p>Autoprint option is necessary because of local practician's demands especially outside of Capital city. There is still strong end user pressure on making hard copies of X ray images.</p> <p>Technical requirements specified in Annex II + III for Lot 2: Digital Mammography units are not changed.</p>
35.	<p>Video Colonoscope</p> <p>Insertion tube outer dia.: &lt; 13 mm</p> <p>Please review if it could read max Dia15mm</p>	<p>This is not acceptable.</p>
36.	<p>Video Colonoscope</p> <p>Working length: approx. 1700 mm</p> <p>This is an unusual length. Please review if it could read "minimum length 1400 mm"</p>	<p>The length of 1,400 mm is acceptable as the specifications provide for an approximate length.</p>
37.	<p>Emergency halogen lamp</p> <p>Halogen is quite outdated. Please specify if other lamps are acceptable as well or if the entire specification of an emergency lamp is redundant</p>	<p>This is not acceptable.</p>
38.	<p>Video system unit: Digital outputs (IEEE, Fire-wire, DV</p>	<p>Any of the output specified is acceptable.</p>

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No	Question	Answer
	<p>etc)</p> <p>Firewire outputs are outdated. Usually DV outputs are used.</p>	
39.	<p>Video system unit</p> <p>Colour adjustment (red, blue etc)</p> <p>Manual colour adjustment is overridden by the automatic white balance specification</p>	<p>Please follow the technical specifications.</p>
40.	<p>Colour LCD monitor:</p> <p>Input: 2x RGB (4xBNC connectors) 1 x Y/C (4-pin mini-DIN), 1 x Composite (BNC connectors)</p> <p>RGB connectors are usually SUB D 15 connectors</p>	<p>Please follow the technical specifications.</p>
41.	<p>System for capturing image and video documentation with the possibility of DICOM and HL 7 interface for integration in the hospital information system (HIS) and hospital network</p> <p>Language: English and Serbian if available</p> <p>Is Serbian language compulsory?</p>	<p>Serbian language, if available</p>
42.	<p>User Manual English and Serbian (if available)</p> <p>Is Serbian language compulsory?</p>	<p>Serbian language, if available</p>
43.	<p>If all products offered in LOT 4 and LOT 7 must originate, as indicated I "Instruction for tenderers" in a Member State of EU or a country covered by the IPA programme? Could the products which do not originate in EU or IPA programme countries be offered as well in this tender? Does this mean that supplies from the non European manufacturers are excluded from this procurement?</p>	<p>All supplies must comply with the rule of origin.</p> <p>The eligible countries covered by the IPA programme are the following:</p> <p>Member States:</p> <p>Austria, Belgium, Bulgaria, Czech Republic, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom.</p> <p>Beneficiaries of this Regulation:</p> <p>Croatia, The former Yugoslav Republic of Macedonia, Turkey, Albania, Bosnia, Montenegro, Serbia, including Kosovo.</p> <p>Beneficiary of the European Neighbourhood and Partnership Instrument:</p>

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No	Question	Answer
		<p>Algeria, Armenia, Azerbaijan, Belarus, Egypt, Georgia, Israel, Jordan, Lebanon, Libya, Moldova, Morocco, Palestinian Authority of the West Bank and Gaza Strip, Russian Federation, Syria, Tunisia, Ukraine.</p> <p>Member State of the European Economic Area:</p> <p>Iceland, Lichtenstein, Norway</p>
44.	<p>Tender Guarantees</p> <p>Could you kindly indicate if it is possible to provide one single tender guarantee covering the total of tender guarantee amounts for all lots we intend to bid or if bidders have to submit separate tender guarantees for each lot?</p>	<p>Both options are acceptable.</p>
45.	<p>Lot 7. Microscopes</p> <p>The technical specifications indicate 'Long life LED illumination (100,000 hours)'.</p> <p>Based on 8 hour workdays this corresponds with approx. 50 year bulb-life. Please confirm 100,000 is a typo and the LED illumination lifetime should be 10,000 hours (which is industry standard for these types of microscopes)</p>	<p>There is a printing error in the technical specification.</p> <p>10,000 h (ten thousand hours) is correct.</p>
46.	<p>Annex II+III documents: Technical specifications + Technical offer, for Lots 1, 2 and 3, page 2, section STANDARDS, it is written: Tenderers shall ensure conformity of the equipment with all applicable Serbian (Medicines and Medical Devices Agency)...” Should tenderer submit the valid licence issued by Medicines and Medical Devices Agency of Republic Serbia in tender as a proof of above mentioned request?</p>	<p>Proof of compliance with technical standards shall be included in the technical documentation for each product offered.</p>
47.	<p>In ANNEX II + III: TECHNICAL SPECIFICATION + TECHNICAL OFFER for LOT 1 (ANALOGUE MAMMOGRAPHY UNIT AND INTEGRATED CR UNIT) - page 1 we found that tenderers are required to demonstrate that specifications of items that they offer are responsive to the requirements set out in the tender dossier and to provide necessary documentation such as catalogues, brochures, booklets that inform of details of technical specifications that sufficiently define the equipments being offered. Do you find manufacturer's written statement informing about technical details of the equipment sufficient?</p>	<p>See answer n.17.</p>
48.	<p>In ANNEX II + III: TECHNICAL SPECIFICATION + TECHNICAL OFFER for LOT 1 (ANALOGUE MAMMOGRAPHY UNIT AND INTEGRATED CR UNIT) - page 2 we found all items supplied shall</p>	<p>Yes manufacturers signed statement is accepted.</p>

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	include full manufacturer warranty granted for a minimum of two (2) years. Do you find manufacturer's statement regarding warranty sufficient?	
49.	In ANNEX II + III: TECHNICAL SPECIFICATION + TECHNICAL OFFER for LOT 1 (ANALOGUE MAMMOGRAPHY UNIT AND INTEGRATED CR UNIT) - page 2 we found that all equipment should have ISO certificate. Do you mean ISO 13485:2003 certificates for Manufacturer? Is it necessary to submit copy of ISO 13485:2003 for the manufacturer and copy of CE certificate (DOC) for the equipment?	Correct.
50.	<p>Also, In ANNEX II + III: TECHNICAL SPECIFICATION + TECHNICAL OFFER for LOT 1 (ANALOGUE MAMMOGRAPHY UNIT AND INTEGRATED CR UNIT) - page 2 we found that tenderers shall ensure conformity of the equipment with all applicable Serbian (Medicines and Medical Devices Agency) and EU technical regulations.</p> <ul style="list-style-type: none"> <li>- ISO 13485:2003 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.</li> <li>- CE Marking on a product is a manufacturer's declaration that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislation. Tenderers cannot ensure this conformity. Only Manufacturers can.</li> </ul> <p>Do you mean tenderers shall prove conformity with all applicable Serbian (Medicines and Medical Devices Agency) and EU technical regulations with submission of copies of ISO certificate, CE certificate and Marketing Authorization Certificate granted by Medicines and Medical Devices Agency of Serbia?</p>	<p>The ISO certificate is requested for the manufacturer of the device.</p> <p>The CE mark is requested for each device offered.</p> <p>Each device offered must have been approved by the Medicines and Medical Devices Agency of Serbia. If not, the device could not be operated in Serbian health institutions.</p>
51.	In ANNEX II + III: TECHNICAL SPECIFICATION + TECHNICAL OFFER for LOT 1 (ANALOGUE MAMMOGRAPHY UNIT AND INTEGRATED CR UNIT) - page 3 we found that tenderers must have a local maintenance and technical support office or a company entrusted to solve any problem on site etc. Is it necessary to prove technical capacity of local maintenance and technical support office with list of service engineers fully employed in a local office or local entrusted company?	<p>Technical specifications request only the following:</p> <p>The tenderer must have a local maintenance and technical support office or a company entrusted to solve any problem on site. The response time must not be more than 24 hours. The name of the company, address, telephone- and fax numbers, e-mail address must be mentioned in the bid.</p> <p>The technical capacity of the local maintenance and technical support office doesn't need to be proved.</p>

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No	Question	Answer
52.	In ANNEX II + III: TECHNICAL SPECIFICATION + TECHNICAL OFFER for LOT 1 (ANALOGUE MAMMOGRAPHY UNIT AND INTEGRATED CR UNIT) - page 3 we found that tenderers shall confirm the availability of spare parts for a period of 5 years beyond the warranty period. Only manufacturer can confirm spare parts availability. Do you ask Manufacturer's statement about availability of spare parts?	A tenderer's declaration in this respect is sufficient.
53.	In ANNEX IV: FINANCIAL OFFER - PUBLICATION REFERENCE for LOT 1 (ANALOGUE MAMMOGRAPHY UNIT AND INTEGRATED CR UNIT) - we found in a table column D that unit costs with delivery should be DDP. Also, we need to express costs for training and maintenance. Taking into consideration local legislative and that this is Donation project and according to Article 8 of General Conditions, is it possible to obtain requisite permits and licenses in order not to pay custom fee and VAT at the customs? Is it possible not to pay VAT for training and maintenance? In other words, do we need to fill in an Annex IV table prices with or without VAT and customs fees?	All supplies and services under this contract will be exempt from Customs taxes and VAT.
54.	In Article 32.3. of ANNEX I - General Conditions it is specified that "The Contractor shall at his own cost make good the defect or damage as soon as practicable. The warranty period for all items replaced or repaired shall recommence from the date on which the replacement or repair was made to the satisfaction of the Project Manager."  Does the "recommencement" mean that warranty shall begin again or resume?	Resume. The warranty period is fixed and starts from provisional acceptance.
55.	Should the warranty be applied only for replaced or repaired spare part, or to be applied for complete system that consist that particular defective or damaged spare part.	The warranty resume only for the parts either replaced or repaired.
56.	If the warranty is applied to particular replaced or repaired spare part, does this warranty should be valid for the same duration of warranty requested in the Tender or it would be applied as separate warranty for replaced part according to general manufacturer warranty conditions in accordance to the requirement for Warranty stated in Annex II + III of each lot?	Please see answers to questions n. 54 and 55.
57.	According to our market research regarding the LOT 7 of the above Tender, we find that microscopes specified as items 7.1, 7.2. and 7.3 do not have their origin in EU. Please make exceptions to the rule on	There is no derogation on the rule of origin for this tender because of the availability of products with EU certificate of origin.

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No	Question	Answer
	origin in this case and approve a derogation. We would like to emphasize that by such derogation the dominant part of the total value of the LOT 7 will remain with EU origin.	
58.	We would like to clarify the paragraph regarding economic operator in the Supply Procurement Notice Section 16 Selection and Award Criteria. We understand that legal entities bidding in the tender could be supported by other companies (e.g. entities within the same group of companies) in the selection criteria based on a specific understanding regarding the resources in question, without the need to create a formal consortium. Kindly confirm if this understanding is correct.	Yes this is correct. A letter of undertaking from these other companies shall be provided in the tender.
59.	Our understanding of “similar projects in nature” requested in “Supply Procurement Notice”, Section 16, Selection and Award Criteria, are those projects which are related to Diagnostic imaging equipment. Please, confirm if this understanding is correct.	Similar project in nature means projects for the supply of similar equipment as in this tender.
60.	We would like to inquire about the readiness of the sites to receive the equipment. The tender documents or the contract draft does not discuss any pre-installation work to be done. Are we correct in assuming that the sites are all ready for installation?	The sites will be ready at the time of delivery of the goods.
61.	We would like to inquire more detail about the insurance policies required. Would a customary transportation insurance generally used in international trade qualify as the transport insurance required to cover ALL risk as specified in the Special terms? What coverage specifically is required from the full comprehensive installation insurance?	It is up to the supplier to decide which insurance policy complies with the requirements of the General and Special conditions in this respect.
62.	A project manager will be appointed to monitor the contract performance with fairly extensive authorization on behalf of the Contracting Authority. We would like to inquire how the project manager will be selected, what are the qualifications of such project manager and if the person will be a third party (etc. a consultant) or an employee of the Contracting Authority	The Contracting Authority will appoint a project manager with the necessary capacity.
63.	We would like to inquire about the termination clause 36.8 in the general conditions of the contract draft. The clause 36.1 seems to include already a fairly extensive list of termination grounds. What kind of situations could be foreseen to result in termination under 36.8? Is there a possibility to be more precise or and make sure the clause could not be used in bad faith?	Termination grounds are only those listed in article 36.1.  Article 36.8 seems to reaffirm what is already foreseen in article 36.1.

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No	Question	Answer
64.	<p>Referring to ANNEX II + III: TECHNICAL SPECIFICATION + TECHNICAL OFFER for LOT 1. - ANALOGUE MAMMOGRAPHY UNITS AND INTEGRATED CR UNIT, for LOT 2. -DIGITAL MAMMOGRAPHY UNITS and for LOT 3. - MAMMOGRAPHIC WORK STATION, the "Operator and Service Manual in English and Serbian language" are requested. Taking into consideration that service manuals are very huge set of many documents and is allowed to be used only by authorized trained service engineers is it acceptable that this requirement does not include Service manual and be corrected into: " Operator manuals in English and Serbian language". Moreover, Operator Manual itself includes some basic service manual data and maintenance instructions and troubleshooting.</p>	<p>This is acceptable.</p>
65.	<p>Referring to ANNEX II + III in TECHNICAL SPECIFICATION for LOT 1. - ANALOGUE MAMMOGRAPHY UNITS AND INTEGRATED CR UNIT, the "Operator key board/console (must include all Serbian characters)" is stated in section for mammography unit.</p> <p>Bearing in mind that there is no standard keyboard having complete set of characters in analog mammography unit and from other hand such keyboard exists in CR unit is it acceptable that such requirement be the part of CR section?</p>	<p>Yes.</p>
66.	<p>Referring to ANNEX II + III: TECHNICAL SPECIFICATION + TECHNICAL OFFER for LOT 2. - DIGITAL MAMMOGRAPHY UNITS, technical specification includes Diagnostic Mammography Review Workstation. Bearing in mind that such workstation is treated as separate medical device in accordance to the EU's and Serbian law regulations, the Marketing Authorization Certificate (Registration Sales License) issued by Medicines and Medical Devices Agency of Serbia is needed. Therefore to our understanding, the tenderer should submit such document in order to comply the tender's request related to the conformity. Is it correct?</p>	<p>The tenderer shall prove that this device is approved by the Medicines and Medical Devices Agency of Serbia.</p>
67.	<p>Referring to ANNEX II + III in TECHNICAL SPECIFICATION section for LOT 2. - DIGITAL MAMMOGRAPHY UNITS, the "LCD monitor resolution of 1289x1024" is requested. Is 1280 x 1024 acceptable?</p>	<p>Yes., this is acceptable</p>
68.	<p>Referring to ANNEX II + III in TECHNICAL SPECIFICATION section for LOT 2. - DIGITAL MAMMOGRAPHY UNITS there are list of some</p>	<p>Yes, correct.</p>

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No	Question	Answer
	<p>parameters that are not in the table. They are as follows:</p> <p>“Image display:</p> <p>After the patient selection, the folder automatically appears and images are loaded. Image display chronologically, including previous images. Image folder widening, when several previous images are available. Image panel allowing a visual control of all mammo patient images, differentiating standard examination, magnification, stereotaxis, screenshot by date, laterality. Patient’s collection creation possibility for next examination discussion or for presentation.</p> <p>Multiple hanging protocol:</p> <p>Autoprefetch of Priors (based on patient worklist, if RIS and PACS is available. Fit to screen function for all images of FFDM, CR and digitized films (the system to recognize automatically the shape of the breast in the image for display Automatic symmetrical alignment of the image (FFDM, CR and digitized films). Local contrast enhancement at the location of mouse cursor. Possibility to put marker on the image.”</p> <p>We understand that all those parameters are also requested to be fulfilled and should belong to the same evaluation process as all others, in other words to be treated in the same way as all others and to be in the table. Is it correct?</p>	
69.	<p>Referring to TECHNICAL SPECIFICATION for LOT 3 - MAMMOGRAPHIC WORK STATION“. The relevant images can be specifically marked (key image marking)” is requested. This parameter is dedicated to CT and MR images and it is not relevant for mammographic images. Is it acceptable to offer annotations of lesions? It is similar technique as requested one, but more accurate way of highlighting relevant information.</p>	<p>Yes, this is acceptable.</p>
70.	<p>Referring to TECHNICAL SPECIFICATION for LOT 3 - MAMMOGRAPHIC WORK STATION the “Software including basic rendering functions (MIP, MPR)” is the parameter that is not relevant for mammographic images. Therefore, our firm cannot offer such feature with mammographic dedicated workstation. We think that this parameter will not be treated as substantial departure which affects the requested technical requirements. Can you confirm this?</p>	<p>Yes, this is confirmed.</p>
71.	<p>Referring to ANNEX II + III: TECHNICAL SPECIFICATION + TECHNICAL OFFER for LOT 1, LOT 2 and LOT3 in section “WARRANTY” we understand that the full standard manufacturer warranty</p>	<p>This is correct; however if there are parts included which bear a warranty period beyond 2 years these have to be mentioned.</p>

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No	Question	Answer
	will be sufficient to be granted for a minimum of 2 years for all items supplied in the Lot. Would you be kind to confirm this?	
72.	<p>TENDER DOCUMENT page 6 of 10 - TENDERER'S DECLARATION(S)            In paragraph 8: "...We confirm that we are not tendering for the same contract in any other form..."</p> <p>Does it indicate that we, as a bidder, can submit only one offer per lot? Since we are distributor of a specific manufacturer, does it mean that other companies worldwide can also offer same manufacturer's equipment? Please clarify.</p>	<p>Yes, only one bid per Lot.</p> <p>Any company fulfilling the terms and conditions of the tender may submit a bid. There can be several bids offering the same brand of equipment.</p>
73.	<p>Clarifications for Lot 1</p> <p>According to our information, only one firm has CR System and Medical Dry Technology Imager with European origin. Because of that firm have monopolistic position which is opposite to the fair competition aim of the open tender procedure. To secure our monopolistic claim, we further state that only that firm as European origin manufacturer has a registered product in Serbian medicines and medical devices Agency for the territory of Serbia. In this way we conclude, that only the bidder that unites with Agfa distributor as a joint venture bidders or similar, qualifies as an appropriate bidder. In this way transparency of tender process and competitiveness between manufacturers is fully ruined.</p> <p>Question and request:</p> <p>Therefore PLEASE restructure the tender requirement with respect to this demand and allow all European manufacturers to compete on this tender.</p>	<p>According to the tender document and the specifications any eligible manufacturer (from all countries eligible under the IPA programme) and any eligible distributor can take part to the tender</p>
74.	<p>LOT 1: ANALOGUE MAMMOGRAPHY UNIT AND INTEGRATED CR UNIT</p> <p>MANDATORY REQUIREMENTS FOR LOT 1 Page 4</p> <p>Service and operation manuals in English and Serbian language.</p> <p>Page 8 General system inclusions</p> <p>Operator manual English + Serbian</p> <p>Tech. documentation English only</p> <p>Pre-installation guide English only 3 of 7</p> <p>Question and request:</p> <p>Please change to: Page 4</p> <p>Service manual in English and operation manuals in</p>	<p>This is acceptable.</p>

**CONTRACTING AUTHORITY'S CLARIFICATIONS No. 1**

No	Question	Answer
	English and Serbian language.	
75.	<p>LOT 1: ANALOGUE MAMMOGRAPHY UNIT AND INTEGRATED CR UNIT</p> <p>MANDATORY REQUIREMENTS FOR LOT 1 Page 4 DOCUMENTS:</p> <p>The following documents shall be delivered for all equipment:</p> <ul style="list-style-type: none"> <li>- Service and operation manuals in English and Serbian language.</li> <li>- Execution guidance / installation drawings.</li> <li>- Certificates of compliance to safety norms and standards and/or trial test results at the manufacturer's facility.</li> </ul> <p>Question and request:</p> <p>Please change to:</p> <p>The following documents shall be delivered for all equipment during equipment delivery:</p> <ul style="list-style-type: none"> <li>- - Service manual in English and operation manuals in English and Serbian language.</li> <li>- - Execution guidance / installation drawings.</li> <li>- - Certificates of compliance to safety norms and standards and/or trial test results at the manufacturer's facility.</li> </ul>	This is acceptable.
76.	<p>LOT 1: ANALOGUE MAMMOGRAPHY UNIT AND INTEGRATED CR UNIT</p> <p>MANDATORY REQUIREMENTS FOR LOT 1 Page 5 Generator: kV range: min. 22 – 35</p> <p>Question and request:</p> <p>Please confirm that following figures can be accepted:</p> <p>kV range: min. 23 – 35</p>	This is acceptable.
77.	<p>LOT 1: ANALOGUE MAMMOGRAPHY UNIT AND INTEGRATED CR UNIT</p> <p>MANDATORY REQUIREMENTS FOR LOT 1 Page 5 mAs range: 4-500 with timer range 0.04-5s</p> <p>Question and request:</p> <p>Please confirm that following figures can be accepted:</p> <p>mAs range: 4-500 with timer range 0.04-7s or mAs range: 4-500 with timer range large focus: 10ms - 4s; small focus: 10ms - 7s</p>	This is acceptable.

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No	Question	Answer
78.	<p>LOT 1: ANALOGUE MAMMOGRAPHY UNIT AND INTEGRATED CR UNIT</p> <p>MANDATORY REQUIREMENTS FOR LOT 1 Page 5 X-Ray tube assembly:</p> <p>Focal spot: 0.1 mm (small) and 0.3 mm (large)</p> <p>Question request:</p> <p>Please confirm that following figures can be accepted:</p> <p>Focal spot: 0.1 mm star pattern or 0.15 IEC (small) and 0.3 mm (large)</p>	<p>This is acceptable.</p>
79.	<p>LOT 1: ANALOGUE MAMMOGRAPHY UNIT AND INTEGRATED CR UNIT</p> <p>MANDATORY REQUIREMENTS FOR LOT 1 Page 6 Automatic exposure control:</p> <p>Location indication with LED display</p> <p>Question and request:</p> <p>As our MammoDiagnost have unlimited variable positions please change to: Location indication with LED display for models which have only min 6 fix detector locations.</p>	<p>This is acceptable.</p>
80.	<p>LOT 1: ANALOGUE MAMMOGRAPHY UNIT AND INTEGRATED CR UNIT</p> <p>MANDATORY REQUIREMENTS FOR LOT 1 Page 7 Safety features</p> <p>Automatic motorized compression release in case of power loss.</p> <p>Question and request:</p> <p>Please remove this characteristic as request.</p>	<p>Changed to read: Automatic motorized or manual decompression release in case of power loss</p>
81.	<p>LOT 1: ANALOGUE MAMMOGRAPHY UNIT AND INTEGRATED CR UNIT</p> <p>MANDATORY REQUIREMENTS FOR LOT 1 Page 7 Safety features</p> <p>Integrated quality control to compensate against changes in film processor and film.</p> <p>Question and request:</p> <p>The exposure parameters at MammoDiagnost needs to be adapted to every film and film processor used for the system. The Service is able to calibrate the MammoDiagnost to the used film and film processor.</p> <p>Please clarify what kind of Integrated quality control</p>	<p>Any kind is acceptable.</p>

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No	Question	Answer
	should be present on the mammo system.	
82.	<p>LOT 1: ANALOGUE MAMMOGRAPHY UNIT AND INTEGRATED CR UNIT</p> <p>MANDATORY REQUIREMENTS FOR LOT 1 Page 7 Recording system</p> <p>Bucky factor: R=5:1, approx. 36 lines/cm</p> <p>Question and request:</p> <p>Please change to:</p> <p>Bucky factor: R=5:1, approx. 31 lines/cm</p>	<p>This is acceptable because the specification provided is an approximate figure.</p>
83.	<p>LOT 1: ANALOGUE MAMMOGRAPHY UNIT AND INTEGRATED CR UNIT</p> <p>MANDATORY REQUIREMENTS FOR LOT 1 Page 8 General system inclusions</p> <p>Operator key board/console (must include all Serbian characters)</p> <p>Question and request:</p> <p>Please change to:</p> <p>Operator key board/console (must include all Serbian Latin characters)</p>	<p>This is acceptable.</p>
84.	<p>LOT 1: ANALOGUE MAMMOGRAPHY UNIT AND INTEGRATED CR UNIT</p> <p>MANDATORY REQUIREMENTS FOR LOT 1 Page 11 CR system:</p> <p>Automatic display of the following image attributes:</p> <ul style="list-style-type: none"> <li>- kVp, - exposure time, - target and filter material, - compression force, - breast thickness, -magnification factor estimated, - source to detector distance, - exposure control method, -sensor position organ doze, - device ID and device type</li> </ul> <p>Question and request:</p> <p>It is not possible to transfer from MammoDiagnost to CR and to automatic display asked image attributes. According to our information there is no any mammo system on the market that enables this feature.</p> <p>Please remove as request.</p>	<p>This is not accepted.</p> <p>This feature is very important for clinical use and is therefore mandatory. Information that there are no mammography systems on the market enabling this feature is not correct. There is a minimum of five manufacturers with European origin on the market producing the mammography units which enable such features.</p>
85.	<p>Clarifications for Lot 2</p> <p>ANNEX II + III: TECHNICAL SPECIFICATIONS + TECHNICAL OFFER LOT 2: DIGITAL MAMMOGRAPHY UNITS MANDATORY</p>	<p>All manuals shall be supplied in English and in Serbian (if available).</p>

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<b>No</b>	<b>Question</b>	<b>Answer</b>
	<p>REQUIREMENTS FOR LOT 2; Page 4</p> <p>Service and operation manuals in English and Serbian language.</p> <p>Question and request:</p> <p>Please change to:</p> <p>Service manual in English and operation manuals in English and Serbian language</p>	
<b>86.</b>	<p>Page 5 X-ray Generator:</p> <p>Power: min. 5kW</p> <p>Question and request:</p> <p>Please confirm that following figure can be accepted:</p> <p>Power: min. 4.7kW</p>	This is not accepted.
<b>87.</b>	<p>Page 7 Collimator</p> <p>FOV to be modified manually.</p> <p>Question and request:</p> <p>Please remove as request.</p>	This is not accepted.
<b>88.</b>	<p>Page 7 Flat panel detector:</p> <p>Size: min. 24 x 30 cm</p> <p>Question and request:</p> <p>Please confirm that following figure can be accepted:</p> <p>Size: min. 23.9 x 30 cm</p>	This is acceptable.
<b>89.</b>	<p>Page 7 Flat panel detector: Image depth: &gt; 13 bit</p> <p>Question and request:</p> <p>Please confirm that following figure can be accepted:</p> <p>Image depth: <math>\geq</math> 13 bit</p>	This is acceptable.
<b>90.</b>	<p>Page 8 Digital acquisition system:</p> <p>Exposure to exposure time: &lt; 30 seconds</p> <p>Question and request:</p> <p>Please confirm that following figure can be accepted:</p> <p>Exposure to exposure time: <math>\leq</math> 30 seconds</p>	This is acceptable.
<b>91.</b>	<p>Page 8 Connectivity:</p> <p>DICOM Query / Retrieve User</p> <p>Question and request</p>	This is not accepted.

**CONTRACTING AUTHORITY'S CLARIFICATIONS No. 1**

No	Question	Answer
	Please remove as request.	
92.	<p>Page 10 Multiple hanging protocol:</p> <p>Fit to screen function for all images of FFDM, CR and digitized films (the system to recognize automatically the shape of the breast in the image for display</p> <p>Question and request</p> <p>Please remove as request.</p>	This is not accepted.
93.	<p>Instruction for tenderers, on page 3, paragraph "Origin": "Unless otherwise provided in the contract supplies must originate in a Member State of the European Union or a country covered by the IPA programme. The origin of the goods must be determined according to the Community Customs Code or the international agreements to 'which the country concerned is a signatory.'" Please, could you explain in details statement: Unless otherwise provided in the contract.", does this means that offered supplies can be originate also out of European Union, for example, if there are no suppliers from EU or leading manufacturers for that kind of equipment are no in EU?</p>	Please read answers n.8 and 43.
94.	<p>Concerning tender with publication reference EuropeAid/129567/C/SUP/RS, in technical specification for LOT 4 - Colonoscopes for technical specification of colonoscopes is characteristic: "Instrument channel inner dia.: &gt;3.7 mm" is this right, or maybe typing mistake, should be "&gt; ", because colonoscopes usually have instrument channel inner diameter of 3,7 mm not „&gt;3J mm"</p>	Please follow the technical specifications.
95.	<p>Special Conditions - Applicable to contract EuropeAid/129567/C/SLrP/RS -LOT 4-Contents- Article 16 - Tax and customs arrangements, second paragraph "For supplies to be imported into the country of the Contracting Authority all duties and taxes applicable to their importation, including VAT shall be excluded."</p> <p>Please, could you explain what mean all duties and taxes shall be excluded from? In this case Contracting Authority is Delegation of the European Union to the Republic of Serbia GTC 19 Avenue Building, Vladimira Popovica 40, 11070 Belgrade, Serbia and if Contractor import into that Country, customs duties and taxes exist, and present component of price structure.</p>	<p>All supplies and services under this contract will be exempt from Customs taxes and VAT.</p> <p>Bids must therefore not include any import taxes into Serbia.</p>
96.	<p>Lot 1: 1.1. Mammography unit</p> <p>The technical specifications of this unit can comply</p>	This is not accepted.

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No	Question	Answer
	<p>with only one brand's product So we kindly request you to put some deviations to the technical specifications according to the following requirement for a more competitive bidding procedure.</p> <p>Tube current is required as 100 mA, we kindly request you to change this specification as 90-100 mA</p>	
97.	<p>For Automatic exposure control min. 6 detector locations is required, can you please clarify if "3 fields electronically selectable" will be acceptable or not?</p>	<p>They will not be acceptable.</p>
98.	<p>For Gantry, digital display for kV, mAs and exposure time required, can you please clarify if "digital display for kV and mAs" will be enough and acceptable?</p>	<p>This is not acceptable.</p>
99.	<p>1.2 CR System and Medical Technology Imager</p> <p>There is only one CR-system which can be used for mammography BUT, being a semi-automatic CR-system it is not suitable for breast cancer screening and diagnostics, therefore there is not solution for this application. So please change the specifications as semi-automatic or application of this unit.</p>	<p>This is not acceptable.</p>
100.	<p>Lot 2</p> <p>2.1 Digital mammography units</p> <p>The technical specification of this unit can comply with only one brand's product. So we kindly request you to put some deviations to the technical specifications according to the following requirement for a more competitive bidding procedure.</p> <p>Can you please clarify if display parameters of kV mAs, target filter will be enough or not?</p>	<p>They will not be enough. Please follow the technical specifications.</p>
101.	<p>Can you please clarify the focal spot: 0.1 - 0.3 is acceptable or not?</p>	<p>Please refer to technical specifications.</p>
102.	<p>Can you please inform us if X-Ray tube target material is only tungsten or tungsten-rhenium is acceptable?</p>	<p>This is not acceptable.</p>
103.	<p>Rotation speed is required min. 8,500 rpm, does it acceptable to be offered 3,000 rpm?</p>	<p>This is not acceptable.</p>
104.	<p>Collimator beam filter is required Mo und Rh. Can you please clarify if Rh and Ag is acceptable or not?</p>	<p>This is not acceptable.</p>
105.	<p>For digital acquisition System, exposure to exposure time is required &lt; 30s, can you please inform us if exposure time 40s, is acceptable or not?</p>	<p>This is not acceptable.</p>

**CONTRACTING AUTHORITY'S CLARIFICATIONS No. 1**

No	Question	Answer
106.	Connectivity-Auto print is required, we kindly request you to omit this requirement for the technical specifications	This cannot be omitted.
107.	According to our market research regarding the LOT 7 of the above Tender, we find that microscopes specified as items 7.1, 7.2., and 7.3 do not have their origin in EU. Please make exceptions to the rule on origin in this case and approve derogation. We would like to emphasize that by such derogation the dominant part of the total value of the LOT 7 will remain with EU origin.	There is no derogation on the rule of origin for this tender because of the availability of products with EU certificate of origin.
108.	<p>LOT № 1 Analogue Mammograph</p> <p>- Please be informed that the specifications contain certain lock outs in favour of one particular brand. This will make it impossible for bidders to offer other brands; thus creating monopolies which is not allowed according to tender procedures. That is why we would like to ask you to confirm whether the following specs would be acceptable as well so alternative brands could be offered:</p> <ul style="list-style-type: none"> <li>- Microprocessor controlled up to 50 or 80kHz</li> <li>- Compression: auto-mode only, fine tuned</li> <li>- Min. 3 detector locations</li> <li>- Manual compression release in case of power failure</li> </ul> <p>Is it really necessary to supply the operator key board/console with Serbian characters because normally speaking these consoles have regular letters?</p>	<p>The changes that you suggest are not acceptable.</p> <p>Except for the automatic motorized or manual decompression release in case of power loss.</p> <p>The keyboard shall be in Serbian Latin letters.</p>
109.	<p>LOT №2 Digital Mammograph</p> <p>- Please be informed that the specifications contain certain lock outs in favour of two particular brands. This will make it impossible for bidders to offer other brands; thus creating monopolies which is not allowed according to tender procedures. That is why we would like to ask you to confirm whether the following specs would be acceptable as well so alternative brands could be offered:</p> <p>X-ray tube: dual track: this can only be provided by two brands who will offer themselves making it impossible for other bidders to participate. Can you remove this feature from the specs or change it to single track to allow other bidders to participate as well.</p>	<p>This is not acceptable.</p> <p>Thick breasts and thin breasts have very different absorption characteristics. Therefore, it is needed to use different X-ray spectra to optimise image quality at lowest possible dose. Dual track anode is the best way to optimize the x-ray spectrum, avoiding un-necessary radiation. This results in dose reduction and that is why this tender requirement must remain unchanged.</p>
110.	Can the feature Focal spots: 4 (four), two on each target be changed to 2 focal spots which is part of single track tube?	The changes that you suggest are not acceptable.
111.	X-ray tube target material: Is Molybdenum material for the X-ray tube also	This is not acceptable.

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<b>No</b>	<b>Question</b>	<b>Answer</b>
	acceptable?	
<b>112.</b>	Item 4.1 Requested: Insertion tube outer dia.: < 13 mm. Is it possible to offer solution 13,2mm because this scope type can be used with the working channel 4,2mm.	This is not acceptable.
<b>113.</b>	Requested: 300 W Xenon lamp, 500 hrs. life time. Is it possible to offer 300W x. lamp BUT with 400 hrs lifetime stated in technical characteristics as minimum?	This is not acceptable.
<b>114.</b>	Requested: Emergency halogen lamp. Is it possible to offer LED lamp?	This is not acceptable.