REPUBLIKA E SHQIPËRISË

MINISTRIA E SHËNDETËSISË
DHE MBROJTJES SOCIALE

CLARIFICATION NO 3

Issued on 19 July 2023

to the bidding documents for the tender Medical Equipment for Hospitals: Lot 1 Apheresis Lot 2 Digital mammography Lot 3 Ophthalmology Lot 4 Phaco equipment

	Request for clarification submitted from potential Bidder	***Legal basis***	***Response to clarification***
1	***LOT 3 Ophthalmology Diode Laser*** Output Power: 30mW – 2000mW Most of available ophthalmic lasers are reaching optimal therapy result through an energy lower than 1500 mW . The requested energy is just a number which only kills competition. There are leader manufacturers like Carl Zeiss which does not meet this requirement. We kindly demand to have this specification modified to have broader and qualitative in this tender. Requested modification: max1500 mW (at cornea)	Bidding documents Section technical Specifications	**Acceptable:** Output Power: 30mW – 1500mW
2	***LOT 3 Ophthalmology Diode Laser*** Exposure Duration: 10ms – 2000ms and Continuous. Any continuous treatment of more than 180 sec will not provide in anyway any better result to therapy, but will just contribute to eye damage. There are leader manufacturers like Carl Zeiss which does not meet this requirement. We kindly	Bidding documents Section technical Specifications	Not acceptable. There are many manufacturers, leaders in ophthalmology fulfilling the criteria.

	demand to have this specification modified to have broader and qualitative in this tender. Requested modification: Exposure Duration: 10 ms – 2500 ms , cw max 180 s		
3	***LOT 3 Ophthalmology Diode Laser*** Modes of operation: a) single shot, b) continuous, c) repeat. Specification related to specific manufacturer. The modification required form our side has no clinical impact at all on the device performance and clinical benefit. Kindly accept our request to promote also broader competition. There are leader manufacturers like Carl Zeiss does not meet this requirement Requested modification: Modes of operation: a) single shot, b) continuous	Bidding documents Section technical Specifications	Not acceptable. There are many manufacturers, leaders in ophthalmology fulfilling the criteria
4	***LOT 3 Ophthalmology Diode Laser*** Repeat Interval: 30ms - 1000ms and single shot. Please kindly refer to the above request.	Bidding documents Section technical Specifications	Not acceptable. There are many manufacturers, leaders in ophthalmology fulfilling the criteria
5	***LOT 3 Ophthalmology Diode Laser*** Cooling: Forced Air with fans. Each manufacturer delivers its own solution for the cooling method which is not impacting at all clinical performance. This requirements is adopted to specific manufacturers and modification required from our side will not impact and reduce the clinical benefits. This also will promote broader competition	Bidding documents Section technical Specifications	**Acceptable:** Forced Air with fans or thermo-electric or equivalent.

	Proposed change: Cooling: Forced Air with fans or thermo-electric		
6	***LOT 3 Ophthalmology Diode Laser*** Voice confirmation in English language Specification related to specific manufacturer. The modification required form our side has no clinical impact at all on the device performance and clinical benefit. Kindly accept our request to promote also broader competition**.** *Proposed change: To be removed*	Bidding documents Section technical Specifications	Not acceptable. It is important the doctors to hear the voice confirmation while they are working and focusing their eyes in the SLIT Lamp or in Indirect ophthalmoscope.
7	***LOT 3 Ophthalmology Diode Laser*** Includes a multifunction foot pedal with 2 programmable side switches (or similar). Again another manufacturer related specification which is not directly related to any clinical performance. The proposed modification from our side is surely neither impacting nor reducing the benefits. Please accept changes for a better competition. Proposed change: Includes a multifunction foot pedal with 2 programmable side switches (or similar), or fixed functions on foot pedal (increase / decrease parameters)	Bidding documents Section technical Specifications	**Acceptable:** Includes a multifunction foot pedal with 2 programmable side switches (or similar), or fixed functions on foot pedal (increase / decrease parameters)
8	***LOT 3, Ophthalmology DIMENSIONAL OCT/ANGIOGRAPHY***	Bidding documents	Not acceptable.

	Retinal imaging methods: COLOR, B / W (Red - Free digital), IR (direct image during OCT tomogram recording). This requirement COLOR, B / W (Red - Free digital) imaging is built up based on a specific manufacturer, Heidelberg. Almost all OCT's, beside what is being brought up by our side are offering IR imaging with great clinical outcome. Keeping the requirement as it is will make impossible to submit an offer for almost everyone else. There are leader manufacturers like Carl Zeiss does not meet this requirement. Proposed change : Retinal imaging methods: COLOR, B / W (Red - Free digital) OR IR (direct image during OCT tomogram recording).	Section technical Specifications	Heidelberg is not the only manufacturer providing this requirements. There are other manufacturers, leaders in ophthalmology that fulfill this requirement.
9	***LOT 3, Ophthalmology DIMENSIONAL OCT/ANGIOGRAPHY*** Color mode with white flash Same reason as above. Lock-out requirement from specific manufacturer. There are leader manufacturers like Carl Zeiss does not meet this requirement. Proposed change : To be removed	Bidding documents Section technical Specifications	**Acceptable:** Removed
10	***LOT 3, Ophthalmology DIMENSIONAL OCT/ANGIOGRAPHY*** Enable fundus photography and external color photography Same reason as above. Lock-out requirement from specific manufacturer. There are leader manufacturers like Carl Zeiss does not meet this requirement. Proposed change: To be removed	Bidding documents Section technical Specifications	Not acceptable. There are many manufacturers, leaders in ophthalmology, including Zeiss. Anyway, in order not to confuse the bidders, we can change this spec. in: "Enable fundus photography"

11	***LOT 3, Ophthalmology* Ophthalmic Microscope for anterior and posterior surgeries** Stereo tubes for surgeon and assistant with independent light paths, 100% lights for each path. In microscopes with camera system 15-20 % of light is reserved for the camera so it is impossible Technologically speaking to have 100% of the light for the stereo tubes. We kindly ask to revise this requirements for broader competition and logical requirements. Proposed change: Stereo tubes for surgeon and assistant with independent light paths, 80-100% lights for each path	Bidding documents Section technical Specifications	**Acceptable:** Stereo tubes for surgeon and assistant with independent light paths, 80-100% lights for each path
12	***LOT 3, Ophthalmology* Ophthalmic Microscope for anterior and posterior surgeries** Binoculars which allow changing position from 0° - 200° Technologically speaking for inverter tubes is possible to tilt only 0° -110°. In order to include a better solution (Inverter tubes) we kindly ask to accept our request to promote broader competition. There are leader manufacturers like Carl Zeiss does not meet this requirement. Proposed change: Binoculars which allow changing position from 0° - 200°or 0° - 110° tilting for the inverter tubes	Bidding documents Section technical Specifications	**Partially Acceptable:** There are many manufacturers, leaders in ophthalmology providing binoculars changing tilting position up to 180° including Zeiss. Binoculars which allow changing position from 0° - 180° tilting for the inverter tubes (0° -110° is for entry level devices)

13	***LOT 3, Ophthalmology* Ophthalmic Microscope for anterior and posterior surgeries** Control of focus, magnification and pupil distance by touch screen or equivalent user Interface. Pupil distance generally is adjusted directly on the tube and both through touch screen user interface. We kindly ask you to change this requirement to promote broader competition. There are leader manufacturers like Carl Zeiss does not meet this requirement. Proposed change: Control of focus, and magnification by touch screen or equivalent user Interface meanwhile pupil distance to be fixed directly on the tube	Bidding documents Section technical Specifications	**Acceptable:** Control of focus, magnification by touch screen or equivalent user Interface. Pupil distance by touchscreen or manually.
14	***LOT 3, Ophthalmology* Ophthalmic Microscope for anterior and posterior surgeries** Possibility for upgrade the system with digital surgical tracking overlays which provide. incision, capsulorhexis, centration and IOL positioning Guidance Centration has to be fixed manually and this is true for almost all manufacturers. We kindly ask you to change this requirement to promote broader competition. There are leader manufacturers like Carl Zeiss does not meet this requirement. Proposed change: Possibility for upgrading the system with digital surgical tracking overlays which provide. incision, capsulorhexis, manual centration and IOL positioning guidance	Bidding documents Section technical Specifications	Not Acceptable: There are many manufacturers, leaders in ophthalmology fulfilling the criteria, including Zeiss.

15	***LOT 3, ELECTRIC OPERATING BED FOR OPHTHALMIC / ORL /*** Electric operating bed for ophthalmic/oral/ maxillofacial surgery with 4 supporting compartments for the head, back, body and legs To promote broader participation we kindly ask You to change the phrase Electric to Electro- Hydraulic. This is due to the fact that is a industry standard electro- hydraulic and this is the technology chosen from almost all manufacturers. Proposed change: Electro-Hydraulic operating bed for ophthalmic/oral/m axillofacial surgery with 4 supporting compartments for the head, back, body and legs	Bidding documents Section technical Specifications	Not acceptable: Electrical solution is superior technology versus electro-hydraulic one. There are many manufacturers, fulfilling the criteria
16	***LOT 3, ELECTRIC OPERATING BED FOR OPHTHALMIC / ORL /*** Minimum dimensions 1800- 2100 mm length 650-800 mm Width The required width in the range of 650-800 mm is a clearly lockout spec since all manufacturers deliver product with less than 650 mm. We kindly ask You to accept this modification in order to promote broader competition. Clinically speaking this width will not help at all. Proposed change: Minimum dimensions 1800- 2100 mm length 550-800mm width	Bidding documents Section technical Specifications	Acceptable: Minimum dimensions 1800- 2100 mm length 550-800mm width
17	***LOT 3, ELECTRIC OPERATING BED FOR OPHTHALMIC / ORL /*** Height movements in the range approx.	Bidding documents Section technical Specifications	The proposed range is acceptable, since our requirements are approx.

	625-900 mm We kindly ask You to accept this modification to promote broader competition. Again clinically speaking this will not affect at all clinical performance. Proposed change: Height movements in the range approx. 525-850 mm		
18	***LOT 3, ELECTRIC OPERATING BED FOR OPHTHALMIC / ORL /*** Head movements in the range approx. - 30°/+35° 255 x 245 mm We kindly ask You to accept this modification to promote broader competition. Clinically speaking this will not affect at all clinical performance since greater angles will not be at use at all in any circumstance. Proposed change: Head movements in the range approx. - 25°/+25°255 x 245 mm	Bidding documents Section technical Specifications	The proposed range is acceptable, since our requirements are approx.
19	***LOT 3, ELECTRIC OPERATING BED FOR OPHTHALMIC / ORL /*** Back movements in the range approx. 0°/+80° 600 x 600 mm We kindly ask You to accept this modification to promote broader competition. Clinically speaking this will not affect at all clinical performance since greater angles will not be at use at all in any circumstance. Proposed change: Back movements in the range approx. 0°/+70° 600 x 550 Mm	Bidding documents Section technical Specifications	The proposed range is acceptable, since our requirements are approx.

20	***LOT 3, ELECTRIC OPERATING BED FOR OPHTHALMIC / ORL /*** Leg movements in the range approx. 0°/-75° 500 x 600 mm We kindly ask You to accept this modification to promote broader competition. Clinically speaking this will not affect at all clinical performance since greater angles will not be at use at all in any circumstance. Proposed change: Leg movements in the range approx. 0°/-70° 500 x 550 mm	Bidding documents Section technical Specifications	The proposed range is acceptable, since our requirements are approx.
21	***LOT 3, ELECTRIC OPERATING BED FOR OPHTHALMIC / ORL /*** ***Total body movements in the range approx. -5°/+35° 450 x 600 mm*** Please kindly consider to remove this requirements which seems over specified an connected to specific manufacturer. Almost no one from manufacturers has this future specified Proposed To be removed	Bidding documents Section technical Specifications	**Acceptable:** *Removed*
22	***LOT 3, ELECTRIC OPERATING BED FOR OPHTHALMIC / ORL /*** To be equipped with a panel for adjusting electrical functions with memory for at least 6 functions We kindly ask You to accept this modification to promote broader competition. Clinically speaking this will not affect at all clinical performance Proposed change: To be equipped with a panel for adjusting electrical functions with memory for at least 4 functions	Bidding documents Section technical Specifications	Not acceptable. There are many manufacturers, leaders in ophthalmology fulfilling the criteria, even with at least 8 functions.

23	***LOT 3, ELECTRIC OPERATING BED FOR OPHTHALMIC / ORL /*** To be equipped with pedals for adjusting electrical functions with memory for at least 3 functions Over specified. We kindly request to accept this modification. This will promote broader competition. Memory functions are available on the panel. Is excessive to request it in the Foot Switch. Proposed change: To be equipped with pedals for adjusting electrical functions	Bidding documents Section technical Specifications	Partially acceptable: To be equipped with pedals for adjusting electrical functions with memory for at least 3 functions or the memory functions to be available on the panel.
24	***LOT 2 DIGITAL MAMMOGRAPHY*** Workstation To be installed in the diagnostic room with monitors with 2 LCD monitors min 19" with 1600x1200 resolution and 2 TB hard disk for image storage. CD / DVD recorder should be included. this point is not well clarified, is it just the Image Acquisition Workstation (AWS) which is a standard part of the mammo unit or the review and reporting station**.** Which requires larger parameters of Monitors which must be at least 5 MP to see the smallest details. Usually these two workstations are separated.		"Workstation To be installed in the diagnostic room with monitors with 2 LCD monitors min 19" with 1600x1200 resolution and 2 TB hard disk for image storage. CD / DVD recorder should be included"