



REPUBLIKA E SHQIPËRISË
MINISTRIA E SHËNDETËSISË
DHE MBROJTJES SOCIALE

ADDENDUM NO 1

Issued on 21 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*

With reference to section ‘Technical Specifications’ in the Bidding documents the following will be amended:

FOR LOT 3 Ophthalmology

No	Current Technical Specification	Amended Technical Specification
1	Diode Laser	Diode Laser
	1. The Diode Laser photo coagulator, is a state of the art Green Laser, easy to use, portable, solid-state Laser.	1. The Diode Laser photo coagulator, is a state of the art Green Laser, easy to use, portable, solid-state Laser.
	2. Treatment Laser: Diode-pumped, frequency-doubled, solid-state laser 3. Operating Wavelength: 532nm, pure green.	2. Treatment Laser: Diode-pumped, frequency-doubled, solid-state laser 3. Operating Wavelength: 532nm, pure green.
	4. Capable to delivery energy through Slit lamp (with adaptation), Laser Indirect Ophthalmoscope and special endo-laser probes.	4. Capable to delivery energy through Slit lamp (with adaptation), Laser Indirect Ophthalmoscope and special endo-laser probes.
	5. Output Power: 30mW – 2000mW.	5. Output Power: 30mW – 1500 mW.
	6. Exposure Duration: 10ms – 2000ms and Continuous.	6. Exposure Duration: 10ms – 2000ms and Continuous.

	7. Modes of operation: a) single shot, b) continuous, c) repeat. 8. Repeat Interval: 30ms - 1000ms and single shot.	7. Modes of operation: a) single shot, b) continuous, c) repeat. 8. Repeat Interval: 30ms - 1000ms and single shot.
	9. Spot size: 50 - 1000 microns. 10. Cooling: Forced Air with fans.	9. Spot size: 50 - 1000 microns. 10. Cooling: Forced Air with fans or thermo-electric or equivalent.
	11. Display: Color LCD display with shots and total energy delivery counter. 12. Two laser ports (RFID or Resistor type).	11. Display: Color LCD display with shots and total energy delivery counter. 12. Two laser ports (RFID or Resistor type).
	13. Voice confirmation in English language.	13. Voice confirmation in English language.
	14. Includes a multifunction foot pedal with 2 programmable side switches (or similar). 15. Includes a metrics (statistics) screen.	14. Includes a multifunction foot pedal with 2 programmable side switches (or similar) or fixed functions on foot pedal (increase / decrease parameters) 15. Includes a metrics (statistics) screen.
	16. Power supply: 220Vac/50Hz	16. Power supply: 220Vac/50Hz
	17. Standards: CE Mark (2017/745/EU), IEC60601-1, IEC60601-2-22 18. Manufacturer certification: ISO13485	17. Standards: CE Mark (2017/745/EU), IEC60601-1, IEC60601-2-22 18. Manufacturer certification: ISO13485
	19. The equipment offered are new, recent years' technology and produced not before 2022.	19. The equipment offered are new, recent years' technology.

2	3 DIMENSIONAL OCT/ANGIOGRAPHY	3 DIMENSIONAL OCT/ANGIOGRAPHY
	3-dimensional OCT /ANGIOGRAPHY with integrated color retinal camera 45° / 35° with a resolution of at least 5M pixels and white flash.	3-dimensional OCT /ANGIOGRAPHY with integrated color retinal camera 45° / 35° with a resolution of at least 5M pixels and white flash.
	The device must operate in high-speed spectral domain mode.	The device must operate in high-speed spectral domain mode.

Axial Scan Rate at least 110,000 A-scans / sec. Ultra maximum image quality (to avoid fixation lags and blurry images).	Axial Scan Rate at least 110,000 A-scans / sec. Ultra maximum image quality (to avoid fixation lags and blurry images).
The source of white and IR light is at least 940 nm. Power supply: 220Vac/50Hz	The source of white and IR light is at least 940 nm. Power supply: 220Vac/50Hz
Standards: CE Mark (2017/745/EU), IEC60601-1 Manufacturer certification: ISO13485	Standards: CE Mark (2017/745/EU), IEC60601-1 Manufacturer certification: ISO13485
RETINA	RETINA
<ul style="list-style-type: none"> • To enable a total image of the retina that allows a wide and deep image of the retina, choroid and vitreous fluid even in highly myopic patients 	<ul style="list-style-type: none"> • To enable a total image of the retina that allows a wide and deep image of the retina, choroid and vitreous fluid even in highly myopic patients
<ul style="list-style-type: none"> • You must enable En-Face technology and the total view (Full range) of the OCT scan. 	<ul style="list-style-type: none"> • You must enable En-Face technology and the total view (Full range) of the OCT scan.
<ul style="list-style-type: none"> • Enable angiography (OCTA) for non-invasive 3D visualization and quantification of retinal vasculature 	<ul style="list-style-type: none"> • Enable angiography (OCTA) for non-invasive 3D visualization and quantification of retinal vasculature
<ul style="list-style-type: none"> • Retinal imaging methods: COLOR, B / W (Red - Free digital), IR (direct image during OCT tomogram recording). 	<ul style="list-style-type: none"> • Retinal imaging methods: COLOR, B / W (Red - Free digital), IR (direct image during OCT tomogram recording).
<ul style="list-style-type: none"> • Axial depth resolution $\leq 5\mu\text{m}$ (in tissue) • Lateral resolution $\leq 15\mu\text{m}$ (in tissue) 	<ul style="list-style-type: none"> • Axial depth resolution $\leq 5\mu\text{m}$ (in tissue) • Lateral resolution $\leq 15\mu\text{m}$ (in tissue)
<ul style="list-style-type: none"> • Transverse resolution $\leq 15\mu\text{m}$ (in tissue) 	<ul style="list-style-type: none"> • Transverse resolution $\leq 15\mu\text{m}$ (in tissue)
<ul style="list-style-type: none"> • Minimum scanning depth (penetration) of at least 4.0 mm in the standard option • Minimum scanning depth (penetration) of at least 6.0 mm in the total option 	<ul style="list-style-type: none"> • Minimum scanning depth (penetration) of at least 4.0 mm in the standard option • Minimum scanning depth (penetration) of at least 6.0 mm in the total option
<ul style="list-style-type: none"> • Scan width 3.0-15.0 mm 	<ul style="list-style-type: none"> • Scan width 3.0-15.0 mm
<ul style="list-style-type: none"> • Dioptric range -15.0D to +15.0D 	<ul style="list-style-type: none"> • Dioptric range -15.0D to +15.0D

<ul style="list-style-type: none"> • Minimum pupil diameter for imaging at least 2.0 mm (OCT) • OCT /A image montage mode with two or four 9x9mm scans • Size of retinal scans 3x3 mm, 6.4x6.4mm, 9x9mm, 12x12mm • Size of disk scans 6x6 mm 	<ul style="list-style-type: none"> • Minimum pupil diameter for imaging at least 2.0 mm (OCT) • OCT /A image montage mode with two or four 9x9mm scans • Size of retinal scans 3x3 mm, 6.4x6.4mm, 9x9mm, 12x12mm • Size of disk scans 6x6 mm
<ul style="list-style-type: none"> • Enable fundus photography in color, Black and White, and Inverse mode • Image resolution ≤ 5 Mega pixels 	<ul style="list-style-type: none"> • Enable fundus photography in color, Black and White, and Inverse mode • Image resolution ≤ 5 Mega pixels
<ul style="list-style-type: none"> • Color and redless scanning mode 	<ul style="list-style-type: none"> • Color and redless scanning mode
<ul style="list-style-type: none"> • Field of view 45 ° and 35 ° for small pupils • Dioptric range -30.0D to +30.0D 	<ul style="list-style-type: none"> • Field of view 45 ° and 35 ° for small pupils • Dioptric range -30.0D to +30.0D
<ul style="list-style-type: none"> • Pupil diameter for imaging at least 4.0 mm normal or at least 3.3 mm small pupil • Outdoor photography 	<ul style="list-style-type: none"> • Pupil diameter for imaging at least 4.0 mm normal or at least 3.3 mm small pupil • Outdoor photography
<ul style="list-style-type: none"> • Color mode with white flash 	
<ul style="list-style-type: none"> • Outdoor photography with Infrared with 940 nm illumination 	<ul style="list-style-type: none"> • Outdoor photography with Infrared with 940 nm illumination
ANTERIOR SEGMENT	ANTERIOR SEGMENT
Enable a total anterior segment image to capture the entire anterior chamber in a single scan External IR imaging to enable assessment of meibomian glands of the upper and lower eyelids without a dedicated imaging device	Enable a total anterior segment image to capture the entire anterior chamber in a single scan External IR imaging to enable assessment of meibomian glands of the upper and lower eyelids without a dedicated imaging device
Determine epithelial, stromal and total thickness in 10 mm corneal sections.	Determine epithelial, stromal and total thickness in 10 mm corneal sections.
To analyze and compare the thickness and number of epithelium for the patient in different visits	To analyze and compare the thickness and number of epithelium for the patient in different visits
<ul style="list-style-type: none"> • To allow imaging of cataract patients. 	<ul style="list-style-type: none"> • To allow imaging of cataract patients.
<ul style="list-style-type: none"> • To provide information on the diagnosis and treatment of patients with dry eyes • Lateral resolution $\leq 18\mu\text{m}$ (in tissues in the standard option) 	<ul style="list-style-type: none"> • To provide information on the diagnosis and treatment of patients with dry eyes • Lateral resolution $\leq 18\mu\text{m}$ (in tissues in the standard option)
$\leq 38\mu\text{m}$ (in tissue in total option)	$\leq 38\mu\text{m}$ (in tissue in total option)

	<ul style="list-style-type: none"> • Minimum scanning depth (penetration) of at least 3.0 mm in the total option • Minimum scanning depth (penetration) of at least 6.0 mm in the total option 	<ul style="list-style-type: none"> • Minimum scanning depth (penetration) of at least 3.0 mm in the total option • Minimum scanning depth (penetration) of at least 6.0 mm in the total option
	<ul style="list-style-type: none"> • Scan length 2.0 mm to 18.0 mm 	<ul style="list-style-type: none"> • Scan length 2.0 mm to 18.0 mm
	GLAUCOMA	GLAUCOMA
	<ul style="list-style-type: none"> • Perform proven glaucoma tests that combine imaging and structural and vascular measurements 	<ul style="list-style-type: none"> • Perform proven glaucoma tests that combine imaging and structural and vascular measurements
	<ul style="list-style-type: none"> • Enable fundus photography and external color photography. 	<ul style="list-style-type: none"> • Enable fundus photography.
	<ul style="list-style-type: none"> • You must enable the glaucoma report, a special report that allows the detection of defects related to the perimeter. 	<ul style="list-style-type: none"> • You must enable the glaucoma report, a special report that allows the detection of defects related to the perimeter.
	<ul style="list-style-type: none"> • It should provide automatic retinal layer segmentation and basic macular and papillary analysis, RNFL and GCL analysis to monitor pathological conditions in glaucoma. 	<ul style="list-style-type: none"> • It should provide automatic retinal layer segmentation and basic macular and papillary analysis, RNFL and GCL analysis to monitor pathological conditions in glaucoma.
	<ul style="list-style-type: none"> • Table with electric movement with internal different fixation points that allows raising and lowering by means of the digital control panel and the installation of the OCT camera and the computer. With dimensions in the range of 900x600x900 mm 	<ul style="list-style-type: none"> • Table with electric movement with internal different fixation points that allows raising and lowering by means of the digital control panel and the installation of the OCT camera and the computer. With dimensions in the range of 900x600x900 mm
	<ul style="list-style-type: none"> • Computer with software for reviewing and analyzing OCT and Fundus images • The possibility of connecting the device to DICOM MWL, DICOM memory 	<ul style="list-style-type: none"> • Computer with software for reviewing and analyzing OCT and Fundus images • The possibility of connecting the device to DICOM MWL, DICOM memory
	<ul style="list-style-type: none"> • Possibility of Network Review Software - Up to 10 workstations 	<ul style="list-style-type: none"> • Possibility of Network Review Software - Up to 10 workstations
	The equipment offered are new, recent years' technology and produced not before 2022.	The equipment offered are new, recent years' technology.

3	ELECTRIC OPERATING BED FOR OPHTHALMIC / ORL / MAXILLOFACIAL	ELECTRIC OPERATING BED FOR OPHTHALMIC / ORL / MAXILLOFACIAL SURGERY
---	--	--

SURGERY	
<ul style="list-style-type: none"> • Electric operating bed for ophthalmic/oral/maxillofacial surgery with 4 supporting compartments for the head, back, body and legs 	<ul style="list-style-type: none"> • Electric operating bed for ophthalmic/oral/maxillofacial surgery with 4 supporting compartments for the head, back, body and legs
<ul style="list-style-type: none"> • Electrically perform the movements of height, head, back, legs, tredelenburg and reverse trendeleburg 	<ul style="list-style-type: none"> • Electrically perform the movements of height, head, back, legs, tredelenburg and reverse trendeleburg
<ul style="list-style-type: none"> • Minimum dimensions 1800-2100 mm length 650-800 mm width. • To withstand a weight of at least 220 kg 	<ul style="list-style-type: none"> • Minimum dimensions 1800-2100 mm length 550-800 mm width. • To withstand a weight of at least 220 kg
<ul style="list-style-type: none"> • The body must be stainless steel material with wheels for necessary movement • Height movements in the range approx. 625-900 mm 	<ul style="list-style-type: none"> • The body must be stainless steel material with wheels for necessary movement • Height movements in the range approx. 625-900 mm
<ul style="list-style-type: none"> • Head movements in the range approx. $-30^{\circ}/+35^{\circ}$ 255 x 245 mm • Back movements in the range approx. $0^{\circ}/+80^{\circ}$ 600 x 600 mm 	<ul style="list-style-type: none"> • Head movements in the range approx. $-30^{\circ}/+35^{\circ}$ 255 x 245 mm • Back movements in the range approx. $0^{\circ}/+80^{\circ}$ 600 x 600 mm
<ul style="list-style-type: none"> • Leg movements in the range approx. $0^{\circ}/-75^{\circ}$ 500 x 600 mm 	<ul style="list-style-type: none"> • Leg movements in the range approx. $0^{\circ}/-75^{\circ}$ 500 x 600 mm
<ul style="list-style-type: none"> • Total body movements in the range approx. $-5^{\circ}/+35^{\circ}$ 450 x 600 mm • Arm movements in the range approx. $-5^{\circ}/+35^{\circ}$ 450 x 600 mm 	<ul style="list-style-type: none"> • Arm movements in the range approx. $-5^{\circ}/+35^{\circ}$ 450 x 600 mm
<ul style="list-style-type: none"> • Tredelenburg and rivers movements in the range $-10^{\circ}/Revers +5^{\circ}$ 	<ul style="list-style-type: none"> • Tredelenburg and rivers movements in the range $-10^{\circ}/Revers +5^{\circ}$
<ul style="list-style-type: none"> • To be equipped with a panel for adjusting electrical functions with memory for at least 6 functions 	<ul style="list-style-type: none"> • To be equipped with a panel for adjusting electrical functions with memory for at least 6 functions
<ul style="list-style-type: none"> • To be equipped with pedals for adjusting electrical functions with memory for at least 3 functions 	<ul style="list-style-type: none"> • 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.

	<ul style="list-style-type: none"> • To be equipped with an internal battery with extension for at least 100 operations. • To be equipped with a sound alarm for warning in case of an electrical problem 	<ul style="list-style-type: none"> • To be equipped with an internal battery with extension for at least 100 operations. • To be equipped with a sound alarm for warning in case of an electrical problem
	<ul style="list-style-type: none"> • To be equipped with an emergency button for immediate stopping in case of medical emergency 	<ul style="list-style-type: none"> • To be equipped with an emergency button for immediate stopping in case of medical emergency
	<ul style="list-style-type: none"> • Power supply: 220Vac/50Hz 	<ul style="list-style-type: none"> • Power supply: 220Vac/50Hz
	<ul style="list-style-type: none"> • Standards: CE Mark (2017/745/EU), IEC60601-1 • Manufacturer certification: ISO13485 	<ul style="list-style-type: none"> • Standards: CE Mark (2017/745/EU), IEC60601-1 • Manufacturer certification: ISO13485
	The equipment offered are new, recent years' technology and produced not before 2022.	The equipment offered are new, recent years' technology.

	Ophthalmic Microscope for anterior and posterior surgeries	Ophthalmic Microscope for anterior and posterior surgeries
	Ophthalmic Microscope for anterior and posterior surgeries (pc 1) Technology which provides independent blending of coaxial and oblique light Illumination field, red reflex zone min 1200 mm ²	Ophthalmic Microscope for anterior and posterior surgeries (pc 1) Technology which provides independent blending of coaxial and oblique light Illumination field, red reflex zone min 1200 mm ²
	Electro-mechanical clutch system	Electro-mechanical clutch system
4	LED light source with minimum of 3 different type: Cool white, warm white, mixed white Range XY, min: X-60mm i Y-60mm	LED light source with minimum of 3 different type: Cool white, warm white, mixed white Range XY, min: X-60mm i Y-60mm
	Focus range, motorized, min 30 mm Magnification, motorized, 0.5x - 2.0	Focus range, motorized, min 30 mm Magnification, motorized, 0.5x - 2.0
	Stereo tubes for surgeon and assistant with independent light paths, 100% lights for each path Binoculars which allow changing position from 0° - 200°	Stereo tubes for surgeon and assistant with independent light paths, 80-100% lights for each path Binoculars which allow changing position from 0° - 180°.
	Assistant scope with independent 5-step magnification from 0.4x - 2,4x UV and IR blocking filters	Assistant scope with independent 5-step magnification from 0.4x - 2,4x UV and IR blocking filters

Control of focus, magnification and pupil distance by touch screen or equivalent user interface	Control of focus, magnification by touch screen or equivalent user Interface. Pupil distance by touchscreen or manually.
Large color LCD display showing images acquired by the microscope camera Store min 25 unique Surgeons profiles	Large color LCD display showing images acquired by the microscope camera Store min 25 unique Surgeons profiles
Foot controller configured for both wired and wireless transfer	Foot controller configured for both wired and wireless transfer
Possibility for upgrade the system with digital surgical tracking overlays which provide incision, capsulorhexis, centration and IOL positioning guidance	Possibility for upgrade the system with digital surgical tracking overlays which provide incision, capsulorhexis, centration and IOL positioning guidance
Possibility for upgrade the system with optical system which provide visualization of the retina (vitreoretinal surgery)	Possibility for upgrade the system with optical system which provide visualization of the retina (vitreoretinal surgery)
Objective lens with working distance of 200mm (f = 200mm) Power supply: 220Vac/50Hz	Objective lens with working distance of 200mm (f = 200mm) Power supply: 220Vac/50Hz
Standards: CE Mark (2017/745/EU), IEC60601-1 Manufacturer certification: ISO13485	Standards: CE Mark (2017/745/EU), IEC60601-1 Manufacturer certification: ISO13485
The equipment offered are new, recent years' technology and produced not before 2022.	The equipment offered are new, recent years' technology.
Accessories	Accessories
1. Integrated 3 CCD HD camera in the Microscope (pc 1)	1. Integrated 3 CCD HD camera in the Microscope (pc 1)
2. Mechanical Non-contact wide angle viewing system needed for vitreoretinal surgery for working distance 200mm (pc 1)	2. Mechanical Non-contact wide angle viewing system needed for vitreoretinal surgery for working distance 200mm (pc 1)
3. Stereoscopic Diagonal Inverter compatible with 2 (pc 1)	3. Stereoscopic Diagonal Inverter compatible with 2 (pc 1)
4. Reduction Lens which optimizes the view of the retina and the limbus (f = 200mm) (pc 1)	4. Reduction Lens which optimizes the view of the retina and the limbus (f = 200mm) (pc 1)

	5. Wide Field High-Definition Lens, max observation angle 60° - 125°, compatible with 2 (pc 1)	5. Wide Field High-Definition Lens, max observation angle 60° - 125°, compatible with 2 (pc 1)
	6. Sterilization tray for non-contact wide angle viewing system (pc 1)	6. Sterilization tray for non-contact wide angle viewing system (pc 1)
	7. Adapter of Non-contact wide-field viewing system compatible with Microscope (pc 1) 8. Base of Non-contact wide-angle viewing system compatible with Microscope (pc 1) The equipment offered are new, recent years' technology and produced not before 2022.	7. Adapter of Non-contact wide-field viewing system compatible with Microscope (pc 1) 8. Base of Non-contact wide-angle viewing system compatible with Microscope (pc 1) The equipment offered are new, recent years' technology.

FOR ALL LOTS the following shall be changed in the technical specifications:

The specification: The equipment offered are new, recent years 'technology and produced not before 2022 shall be amended to read: The equipment offered are new, recent years' technology

No	Current Technical Specification	Amended Technical Specification
1	Section II - Bid Data Sheet (BDS) viii. Declaration that the equipment offered are new, recent years' technology and produced not before 2022.	Section II - Bid Data Sheet (BDS) Declaration that the equipment offered are new, recent years' technology

ITB 37.1	Original Clause	Amended/ corrected Clause
	<p>(b) Specific Experience: The Bidder shall demonstrate that it has successfully completed at least 3 [three] contracts, within the last 3 years [three years] (for each Lot) prior to bid submission deadline. At least one of the contracts (of each Lot) with a value of</p> <p>69, 000 Euro for Lot 1 Apheresis 181,000 Euro for Lot 2 Digital mammography 298, 000 Euro for Lot 3 Ophthalmology 107, 000 Euro for Lot 4 Phaco equipment</p> <p>The contracts have been successfully and substantially completed and should be similar in nature and complexity to the Goods and Related Services under the Contract. For a joint venture, this requirement may be met by all members combined. Copies of these contracts should be submitted by the Bidder as a proof of this requirement along with the invoices (when contract is signed with private entities) or reference letter (when the contract is signed with public entity).</p>	<p>(b) Specific Experience: The Bidder shall demonstrate that it has successfully completed at least 3 [three] contracts, within the last 3 years [three years] (for each Lot) prior to bid submission deadline. At least one of the contracts (of each Lot) with a value of</p> <p>34, 700 Euro for Lot 1 Apheresis 90,000 Euro for Lot 2 Digital mammography 149, 000 Euro for Lot 3 Ophthalmology 53, 000 Euro for Lot 4 Phaco equipment</p> <p>The contracts have been successfully and substantially completed and should be similar in nature and complexity to the Goods and Related Services under the Contract. For a joint venture, this requirement may be met by all members combined. Copies of these contracts should be submitted by the Bidder as a proof of this requirement along with the invoices (when contract is signed with private entities) or reference letter (when the contract is signed with public entity).</p>

All other requirements in the BDs remain unchanged.