

Annex D. Endoscopic set

1. The equipment must be new, not in operation (Bidder must provide a letter of guarantee).
2. The goods offered by the Bidder must be entered into the State Register of medical equipment and medical devices and / or put into circulation in accordance with the legislation in the field of technical regulation and conformity assessment in the manner prescribed by law.

For confirmation, the Bidder must provide copies of the documents below, or a letter of guarantee that one of the following documents will be provided during delivery:

- a) *a certified copy of the declaration or a copy of documents confirming the possibility of putting into circulation and / or operation (use) of a medical device based on the results of passing the conformity assessment procedure in accordance with the requirements of technical regulations at the time of submission of proposals or signing a purchase agreement or upon delivery, or*
- b) *considering the requirements of the resolutions of the Cabinet of Ministers of Ukraine dated 02.10.2013 № 753 *, №754 **, №755 ***, if the Bidder offers medical devices that have passed state registration, entered in the State Register of Medical Equipment and Medical Devices and allowed for use in the territory of the country and have been put into circulation before the date of mandatory application of technical regulations, it is allowed to offer such products before their expiration date and not more than five years from the date of entry into circulation, without undergoing conformity assessment and labeling national mark of conformity.*

** - Resolution of the Cabinet of Ministers of Ukraine dated 02.10.2013. № 753 "On the consolidated technical regulations of medical viruses".*

*** - Resolution of the Cabinet of Ministers of Ukraine dated 02.10.2013 No. 754 "On the consolidation of the Technical Regulations of Medical Viruses for In Vitro Diagnostics".*

**** - Resolution of the Cabinet of Ministers of Ukraine dated 02.10.2013. № 755 "On the consolidation of the Technical Regulations for active medical virobivs that implant".*

3. Warranty period for devices and optics - not less than 12 months from the date of commissioning (provide a letter of guarantee from the bidder as part of the tender offer).

4. Availability of instructions in Ukrainian or Russian on the devices (provide the original or a copy of the letter of guarantee from the bidder as part of the tender offer).

5. The ability of the participant to supply the proposed equipment must be confirmed by the original letter of guarantee from the manufacturer (if the participant is not the manufacturer of the goods) or his official representative in Ukraine (such representation must be confirmed by a copy of the corresponding letter, order, authorization, etc. from the manufacturer), which confirms the possibility of the participant supplying the proposed equipment in the required quantity, quality and within the timeframe determined by this tender documentation and the participant's proposal (provide a scanned copy of the original letter of guarantee as part of the tender proposal).

№	Specification	Compliance (yes / no) with reference to the documentation
1	Endoscopic processor	
1.1	General requirements for endoscopic processors	
	The endoscopic processor is designed for use with video endoscopes and light source for endoscopy, endoscopic diagnostics	
	This endoscopic system inherits the principle of highly transparent and high-quality display of acquired images, combined with a modern and reliable design	
	The system is equipped with a powerful processor that allows quick processing high-resolution images in real time.	
	The system is equipped with a powerful HD image sensor for the most detailed and clear display of video and photo files	
	Low power consumption and a wide range of interfaces for connecting various equipment qualitatively improve the process of using the video endoscopic system.	
	White balance switch setting, compliance: the device is suitable for independent (automatic) white balance control. Easy and comfortable adjustment, without the need for effort	
	Focus adjustment function: to select the focus in the brightest or central place of the field of view (general and peak mode)	
	Picture tone adjustment function: the function can be adjusted to meet user requirements	
	Freeze function: it is possible to create a freeze frame in real time with the ability to view and scroll	
	General highlighting function: the function allows a clearer view and identification of pathological formations.	
	Enhancing the clarity of the venous coverage by HbE (hemoglobin): the function of increasing the contrast of the venous covering of the mucosa using blood hemoglobin, which increases the quality contrast.	
	USB interface and data export function: the device can store up to 500 GB of information on an external drive.	
	Image stabilization function: Ensuring bright and clear images with maximum cleaning and control of defective pixels	
	Ergonomic design: ergonomic and easy to use device	
	Function of structural vision: function of visualization of venous coverage and tissue structure to make the image more clear	
1.2	Specifications	

1.2.1	General characteristics	
	Dimensions (L * W * H), compliance: 420 * 390 * 165 mm	
1.2.2	Electrical system	
	Voltage: 100 - 240V (± 10%)	
	Frequency: 50/60 Hz	
	Power consumption: 50VA	
1.2.3		
	Video format, compliance: Y / C, DVI, RGB, SYNC, AV	
	Improving image quality: profile improvement, increasing the sharpness of endoscopic images	
	Color tone adjustment: "R" and "B" adjustment ± 50 steps	
	Brightness adjustment: "Y" adjustment ± 50 steps	
	Freeze frame: the ability to perform a freeze frame of endoscopic images, with the ability to view and scroll	
	Measurement mode: general, peak	
	Adjust white balance: Use the white balance switch	
	Magnification control: OFF, 1, 2 and 3	
1.2.4	Air pump (compatibility)	
1.2.4.1	General characteristics	
	Air pressure: 30 - 80 kPa	
	Air flow: 4 - 10 l / min.	
	Work intensity: high and low	
1.2.4.2	Power supply	
	Voltage: 110 / 220V (± 10%)	
	Frequency: 50/60 Hz	
2	Light source	
2.1	General light source requirements	
	Power switch with indicator: used to turn the light source on and off.	
	Paired brightness adjustment button, matching: to increase or decrease the light intensity.	
	Air Pump Power Switch: Used to turn the pump on and off.	
	Air Pump Button: Used to adjust the intensity level of the air pump.	
	The device supports the following performance characteristics: high color temperature, long service life and low power consumption, although the reproduced images are as clear as possible with support for widescreen display.	
	It is possible to adjust the brightness; presence of the electronic mode of change of brightness of light, conformity	
	The device is equipped with an air pump for surgical use, which supports two-speed air flow, is convenient for clinical use and cleaning.	

	There is an integrated function to display the service life of the LED lamp in order to remind users of the service life of the LED lamp during normal use of the product.	
2.2	Specifications	
2.2.1	General information	
	Service life: ≥5 years	
2.2.2	Electrical system	
	Voltage: AC100 - 240V	
	Frequency: 50/60 Hz	
	Input current: 70VA	
2.2.3	Lighting	
	Lamp type: LED lamp	
	Lamp power: 36 watts	
	Luminous flux: 60 lumens	
	Light transmission index: ≥90Ra	
	Color temperature: 3000 - 7000K	
	Type of cooling: forced air cooling	
2.2.4	Air pump	
	Air supply pressure: 30 - 80 kPa, adjustable	
	Flow rate, L - low level: 4 l / min.	
	Flow rate, H - high level: 7 l / min.	
3	Video colonoscope	
3.1	General requirements for a video colposcope	
	The video colonoscope is used to examine the inner surface of the colon and perform diagnostic and therapeutic manipulations in the intestinal cavity under visual control.	
	The distal end of the video colonoscope is soft and flexible, which is why when inserted into the functional parts of the human body, the device does not cause any injuries and does not cause noticeable discomfort.	
	Purpose: videocolonoscope is suitable for observation and diagnosis of various diseases in patients of a wide age range	
	Functionality: Rotary switch (up / down), Direction switch (up / down), Direction switch (left / right), Rotation switch (left / right), Inlet part mark, Flexible section, Aspiration valve, Air / valve Water bottle connector, Fiber optic, Electrical connector, S-cable connector, Suction connector	
	Disinfection, 75% ethanol: yes	
	Disinfection, glutaraldehyde alkaline (immersion): yes	
	Disinfection, chlorhexidine,: yes	

3.2	Specifications	
3.2.1	Productivity	
	Field of view: 140 °	
	Viewing angle: 0 ° (forward aiming)	
	Depth of vision: 3 - 100 mm	
	Working length: 1650 mm	
	Outer diameter of the distal end: Ø12.8 mm	
	Outer diameter of the introductory part: Ø12.8 mm	
	Internal diameter of the tool channel: Ø3.7 mm	
	Flexible section bending ranges: up: 180 °, down: 180 °, left: 160 °, right: 160 °	
3.2.2	Other information	
	Water supply volume: ≥45 ml / min.	
	Gas supply volume: ≥800 ml / min.	
	Aspiration volume: ≥400 ml / min.	
4	Complete set	
	HD Endoscopic processor VME 2800: 1 set	
	LED Light source LLS-2800: 1 set	
	VME-1650S video colonoscope: 1 set	
	Trolley: 1 set	
	19 " Medical Monitor: 1 set	

Warranty: 24 months.

Delivery, training of specialists and commissioning are included in the cost of equipment.

