# **Annex – 6 Technical Specifications for Invitation to Bid (ITB) No.UNFPA/UKR/ITB/24/07**

|  |  |
| --- | --- |
| 1. **Fetal/Maternal monitor** | **Quantity, pcs:** |
| **Product Description**  Fetal/Maternal monitoring provides graphic and numeric information on Maternal and fetal physiological parameters to help clinical personnel assess fetal and maternal well-being.  **Electrical Requirements:**   * Power requirements according to Ukraine standards: 220 VAC ± 10%, 50 Hz. * Power cord with “F” type plug for medical devices. * Built-in rechargeable battery, allowing at least 2 hours of continuous operation.   **Technical specifications:**   * LCD or TFT color screen of at least 12", for waveforms, menus, alarms, and physiological measurement parameters. * Monitored parameters:   + Continuous monitoring of fetal heart rate (FHR) by ultrasonic pulsed doppler.   In the range of at least 50-210 bpm, resolution 1 bpm, and accuracy of at least +/- 2 bpm.  One (1) FHR ultrasound transducer included.   * + Maternal heart rate and electrocardiogram. Heart rate measured in the range of 30 - 240 bpm, resolution 1 bpm, and accuracy of at least +/- 2 bpm.   ECG cable included.   * + TOCO. Measured in the range of 0-100 relative units, resolution of 1 unit. Toco-transducer zeroing.   Toco-transducer waterproof included.   * + Fetal movement. Automatic fetal movement and Manual fetal movement   Fetal movement mark button included.   * + Maternal non-invasive blood pressure (NIBP). Display systolic, diastolic, and main pressure.   Pressure measuring ranges: Systolic: 50 – 240mmHg; Mean: 25 – 200mmHg; Diastolic: 15 – 180mmHg. Accuracy: ±8mmHg or ±5%, whichever is greater  Measurement mode: manual / automatic NIBP measurement  NIBP reusable cuff adult size with tube included.   * + Maternal oxygen saturation (SpO2).   Measured in the range of 70 - 99%, accuracy: ±3%  Spo2 reusable probe with cable included.   * + Maternal pulse rate. Measuring range: 40 bpm – 240 bpm. Accuracy: ±2 bpm or ±5%, whichever is greater   + Maternal respiration (RESP). Measurement method: thoracic impedance   + Maternal body temperature (TEMP). Measured in the range of 0-50°C, resolution 0.1°C.   Temperature reusable sensor included.   * Display shows at least: Fetal heart rate (FHR), TOCO, Fetal movement, Pulse rate (MHR), Maternal blood oxygen (SPO2), Maternal blood pressure (NIBP), Maternal electrocardiogram (ECG), Maternal respiration (RESP), Maternal body temperature (TEMP).   + - Alarms for at least:     - FHR1 high / low     - FHR2 high / low     - Systolic pressure high / low     - Diastolic pressure high / low     - SpO2 high / low     - Pulse rate high / low     - Respiration high / low     - Body temperature high / low     - Technical alarms * Fetal awakening stimulator included. * Automatic detection of transducers. * Ultrasound frequency: 1 MHz +/- 10%. * Intensity of the ultrasound not greater than 5 mW / cm2. * Automatic self-test. * Integrated thermal printer with automatic and manual print-out modes.   + Suitable for 152 mm paper   + Print at least FHR, maternal heart rate, electrocardiogram, TOCO, fetal movement mark, SpO2, Temperature, Pressure (SYA, DIA, MAP), marked events, and alarms.   + Print speeds 1, 2 and 3 cm/min * All materials resistant to disinfection with hospital-grade products. * Indications and messages on the equipment must be in English language as mandatory, and preferably also in Ukrainian language.   **Accessories:**   * Two (2) adjustable belts for ultrasound and toco transducer. * Twenty-four (24) pieces of thermal recording paper. * Two (2) SpO2 reusable probes, in addition to that included in the equipment. * ECG reusable cable, in addition to that included with the device. * Three thousand six hundred (3600) self- adhesive ECG electrodes, adult size. * Three (3) NIBP adult reusable cuffs, in different sizes, in addition to that included with the device. * Twenty (20) bottles of ultrasound gel. * Trolley for the Fetal/Maternal Monitor. * Chassis and external components must be built of materials, and/or have a finish/coating resistant to corrosion and the application of disinfectants commonly used in healthcare premises.   *NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product during the first 12 months, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included and listed in the offer.* | 2 |
| **Documentation required:**  Bidder shall furnish the following documents:   * Manufacturer brochure or data sheet including at least all technical specifications required. * User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal. * Service manuals must be provided including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits. * List of all common spare parts and accessories with part numbers. * Manufacturer authorization Letter. * Commitment manufacturer letter including:   + installation and commissioning on site would be performed by the manufacturer or his representative in the country (according to the general requirements in the bid document under the clause “Installation and commissioning on site").   + at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause “Warranty").   + at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause “Post-sale Services").   + training on use, cleaning, and disinfecting for the healthcare staff, and basic maintenance for the technical staff, in Ukrainian and English language (according to the general requirements in the bid document under the clause “Training").   **NOTE: All the documents must be submitted in English and Ukrainian language as mandatory. The Russian language could be accepted as an exception to the Ukrainian language.** |  |
| **Regulatory approvals required:**  Bidder shall furnish **documentary evidence** to demonstrate that the good offered is approved according:   * Valid certificate or approval letter from national Ukrainian regulatory body, which confirms local registration of the product and permission to use it in medical practice. * Valid manufacturing licenses. * And at least one of the following regulatory approvals and certificates:   + European Certificate of Conformity (CE) with Regulation 2017/745 or Directive 93/42 EC and Agreement Letter signed with the NB demonstrating the on-going MDR application, for Class IIb devices, or   + FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or   Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan. |  |
| **Safety & product Standards:**  Bidder shall furnish the following documents:   * Valid ISO 13485 certificate. * Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety & regulatory standards:   + IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance   + IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests   + IEC 60601-2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment |  |
| 1. **Multiparametric Patient Monitor** | **Quantity, pcs:** |
| **Product Description**  Device intended for use to measure basic physiologic parameters and track the status of adult, pediatric and neonatal patients.  **Electrical Requirements:**   * Power requirements according to Ukraine standards: 220 VAC ± 10%, 50 Hz. * Power cord with “F” type plug for medical devices. * Built-in rechargeable battery, allowing at least 2 hours of continuous operation.   **Technical specifications:**   * For use in adult, pediatric and neonatal patients. * Automatic setting of alarm limits and cuff pressure limits for each type of patient. * Monitoring at least: ECG and Heart Rate (HR), Respiratory Rate (RR), Oxygen Saturation (SpO₂), non-invasive blood pressure, and Temperature. * LCD TFT color display, at least 12”. * Display of at least 5 waveforms and numeric parameters simultaneously. * Configurable display. * Defibrillator shock protection. * Trend storage of at least 120 hours. * Availability of a USB port for installing program updates and for recording parameters * ECG:   + 3 and 5 leads, user selectable.   + ECG main cable (if applicable) and two (2) sets of patient cable terminals (1 neonatal/pediatric, 1 adult if applicable), included.   + Simultaneously display a minimum of 2 ECG traces, and HR value.   + Heart rate measurement range. Adult: at least 25 – 250 bpm, pediatric and neonatal: at least 30 – 300 bpm. Accuracy: ± 1% or ± 5 bpm, whichever is greater.   + S-T segment and arrhythmia analysis.   + Filter for at least diagnostic and monitoring.   + Pacemaker detection   + Lead off condition detected and displayed.   + Adjustable sweep speed * Respiration:   + Technique: transthoracic impedance   + Measurement range: at least 6 – 120 rpm   + Resolution: 1 rpm   + Display of waveform, and RR value. * Noninvasive blood pressure:   + Technique: oscillometric   + Four (4) reusable blood pressure cuffs (S, M, L, XL) with one (1) main hose included.   + Manual and automatic measurement, with configurable intervals.   + Display diastolic, systolic, and average pressure.   + Measurement range.     - * Adults. Systolic: at least 40 – 250 mmHg, Diastolic: at least 10 – 210 mmHg. Maximum mean error: ± 5 mmHg       * pediatric. Systolic: at least 30 – 180 mmHg, Diastolic: at least 10 – 150 mmHg. Maximum mean error: ± 5 mmHg       * Neonatal. Systolic: at least 30 – 130 mmHg, Diastolic: at least 10 – 100 mmHg. Maximum mean error: ± 5 mmHg * Pulse oximetry:   + Measurement range: 0 – 100%. Resolution: 1%, SpO2. Accuracy at least ± 3% within the range 70 – 100%   + Pulse rate: 30 – 250 bpm, resolution: 1 bpm.   + Display of percentage of oxygen saturation, plethysmography curve and heart rate.   + Main cable of SpO2, if applicable, included.   + One (1) SpO2 sensor, reusable clip-on type adult size, included. * Temperature:   + Cutaneous / abdominal.   + Two temperature measurement channels: T1, T2, ∆T   + Measurement range: at least 0 - 45°C. Accuracy: ± 0.1° C. Resolution: 0.1°C   + Four (4) skin and esophageal temperature probes, reusable, 1 of each adult and 1 of each pediatric included. * Alarms:   + Audio-visual alarms for all monitored parameters   + Adjustable high and low alarm limits for all monitored parameters.   + Temporary silence functions.   + Leads-off or sensor disconnect.   + Apnea alarm.   + AC status and low battery * Automatic self-test. * All materials resistant to disinfection with hospital-grade products. * User interface on the equipment must be in English language as mandatory, and preferably also in Ukrainian language. * The monitor should be placed on a trolley. Chassis and external components must be built of materials, and/or have a finish/coating resistant to corrosion and the application of disinfectants commonly used in healthcare premises.   **Accessories:**   * Twelve (12) Reusable cuff sizes S, M, L and XL (three units of each size) in addition to that provided with the device. * One (1) host for NIBP, in addition to that provided with the device. * ECG main cable (if applicable), in addition to that provided with the device. * Three (3) sets of ECG patient cable terminals (2 adult, 1 neonatal/pediatric if applicable), in addition to that provided with the device. * Two hundred (200) disposable self-adhesive ECG electrodes * One (1) skin temperature sensor, reusable, adult size, in addition to that provided with the device. * One (1) Main cable of SpO2 (if applicable) in addition to that provided with the device. * Three (3) SpO2 sensor adult size, reusable clip-on type, in addition to that provided with the device. * Trolley for the Multiparametric Patient Monitor. * Chassis and external components must be built of materials, and/or have a finish/coating resistant to corrosion and the application of disinfectants commonly used in healthcare premises.   *NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product during the first 12 months, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included and listed in the offer.* | 2 |
| **Documentation required:**  Bidder shall furnish the following documents:   * Manufacturer brochure or data sheet including at least all technical specifications required. * User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal. * Service manuals must be provided including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits. * List of all common spare parts and accessories with part numbers. * Manufacturer authorization Letter. * Commitment manufacturer letter including:   + installation and commissioning on site would be performed by the manufacturer or his representative in the country (according to the general requirements in the bid document under the clause “Installation and commissioning on site").   + at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause “Warranty").   + at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause “Post-sale Services").   + training on use, cleaning, and disinfecting for the healthcare staff, and basic maintenance for the technical staff, in Ukrainian and English language (according to the general requirements in the bid document under the clause “Training").   **NOTE: All the documents must be submitted in English and Ukrainian language as mandatory. The Russian language could be accepted as an exception to the Ukrainian language.** |  |
| **Regulatory approvals required:**  Bidder shall furnish **documentary evidence** to demonstrate that the good offered is approved according:   * Valid certificate or approval letter from national Ukrainian regulatory body, which confirms local registration of the product and permission to use it in medical practice. * Valid manufacturing licenses. * And at least one of the following regulatory approvals and certificates:   + European Certificate of Conformity (CE) with Regulation 2017/745 or Directive 93/42 EC and Agreement Letter signed with the NB demonstrating the on-going MDR application, for Class IIb devices, or   + FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or   Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan. |  |
| **Safety & product Standards:**  Bidder shall furnish the following documents:   * Valid ISO 13485 certificate. * Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety & regulatory standards:   + IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance   + IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests   + IEC 60601-2-49: Medical Electrical Equipment - Part 2-49: Particular Requirements for the Basic Safety and Essential Performance of Multifunction Patient Monitoring Equipment. |  |
| 1. **Neonatal patient monitor** | **Quantity, pcs:** |
| **Product Description**  Device intended for measuring basic physiologic parameters and tracking the status of neonatal patients.  **Electrical Requirements:**   * Power requirements according to Ukraine standards: 220 VAC ± 10%, 50 Hz. * Power cord with “F” type plug for medical devices. * Built-in rechargeable battery, allowing at least 210 minutes of continuous operation.   **Technical specifications:**   * For use in neonatal patients. * Automatic setting of alarm limits * Monitoring at least: ECG and Heart Rate (HR), Respiratory Rate (RR), Oxygen Saturation (SpO₂), non-invasive blood pressure, and Temperature. * Color TFT-LCD display, Touchscreen, at least 8”. * Display of at least 6 waveforms and numeric parameters simultaneously. * Configurable display. * Neonatal Apnea Monitoring with vibrating stimulation to wake up. * Anti-motion and anti-low perfusion blood measurement technologies * Monitoring oxygen concentration. Measurement Range 0 – 100%. Resolution ±1%. Sensor included. * Defibrillator shock protection. * Trend storage of at least 120 hours. * Availability of a USB port for installing program updates and for recording parameters * ECG:   + Neonatal 3-Lead ECG cable reusable, included.   + ECG main cable (if applicable), included.   + Simultaneously display a minimum of 2 ECG traces, and HR value.   + Heart rate measurement range. At least 15 – 300 bpm.   + S-T segment and arrhythmia analysis.   + Filter for at least diagnostic and monitoring.   + Pacemaker detection   + Lead off condition detected and displayed.   + Adjustable sweep speed * Respiration:   + Technique: transthoracic impedance   + Measurement range at least 7-150 bpm. Resolution: 1 bpm   + Display of waveform, and RR value.   + Apnea alarm * Noninvasive blood pressure:   + Technique: oscillometric   + Anti-motion technology   + Three (3) neonatal reusable blood pressure cuffs (in 3 different sizes) with one (1) main hose included.   + Manual and automatic measurement, with configurable intervals.   + Display diastolic, systolic, and average pressure.   + Neonate measurement range: 10-150 mmHg * Pulse oximetry:   + Measurement range: 1 – 100%. Resolution: 1%, SpO2. Accuracy at least ± 2% within the range 70 – 100%   + Pulse rate: 30 – 300 bpm, resolution: 1 bpm.   + Display of percentage of oxygen saturation, plethysmography curve and pulse rate.   + Main cable of SpO2, if applicable, included.   + SpO2 neonatal size sensor, reusable, included. * Temperature:   + Cutaneous / abdominal.   + Two temperature measurement channels: T1, T2, ∆T   + Measurement range: at least 0 - 45°C. Accuracy: ± 0.2° C. Resolution: 0.1°C   + Two (2) temperature sensors: skin and esophageal, reusables, 1 of each, neonatal size, included. * Alarms:   + Audio-visual alarms for all monitored parameters   + Adjustable high and low alarm limits for all monitored parameters.   + Temporary silence functions.   + Leads-off or sensor disconnect.   + Apnea alarm.   + AC status and low battery * Automatic self-test. * All materials resistant to disinfection with hospital-grade products. * User interface on the equipment must be in English language as mandatory, and preferably also in Ukrainian language.   **Accessories:**   * Nine (9) neonatal reusable blood pressure cuffs (in 3 different sizes), in addition to that provided with the device. * One (1) host for NIBP, in addition to that provided with the device. * One (1) ECG main cable (if applicable), in addition to that provided with the device. * Two (2) Neonatal 3-Lead ECG cable reusable, in addition to that provided with the device. * Three hundred seventy (370) disposable self-adhesive ECG electrodes, neonatal size * One (1) skin temperature sensor, reusable, neonatal size, in addition to that provided with the device. * One (1) esophageal temperature sensor, reusable, neonatal size, in addition to that provided with the device. * One (1) Main cable of SpO2 (if applicable) in addition to that provided with the device. * Three (3) SpO2 neonatal size sensors, reusable, in addition to that provided with the device. * Three hundred (300) wrap-type disposable neonatal SpO2 sensors. * One (1) oxygen concentration sensor, in addition to that provided with the device. * One (1) apnea awakening sensor (vibration sensor control asphyxia), in addition to that provided with the device. * Trolley for the Neonatal patient monitor * Chassis and external components must be built of materials, and/or have a finish/coating resistant to corrosion and the application of disinfectants commonly used in healthcare premises.   *NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product during the first 12 months, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included and listed in the offer.* | 3 |
| **Documentation required:**  Bidder shall furnish the following documents:   * Manufacturer brochure or data sheet including at least all technical specifications required. * User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal. * Service manuals must be provided including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits. * List of all common spare parts and accessories with part numbers. * Manufacturer authorization Letter. * Commitment manufacturer letter including:   + installation and commissioning on site would be performed by the manufacturer or his representative in the country (according to the general requirements in the bid document under the clause “Installation and commissioning on site").   + at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause “Warranty").   + at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause “Post-sale Services").   + training on use, cleaning, and disinfecting for the healthcare staff, and basic maintenance for the technical staff, in Ukrainian and English language (according to the general requirements in the bid document under the clause “Training").   **NOTE: All the documents must be submitted in English and Ukrainian language as mandatory. The Russian language could be accepted as an exception to the Ukrainian language.** |  |
| **Regulatory approvals required:**  Bidder shall furnish **documentary evidence** to demonstrate that the good offered is approved according:   * Valid certificate or approval letter from national Ukrainian regulatory body, which confirms local registration of the product and permission to use it in medical practice. * Valid manufacturing licenses. * And at least one of the following regulatory approvals and certificates:   + European Certificate of Conformity (CE) with Regulation 2017/745 or Directive 93/42 EC and Agreement Letter signed with the NB demonstrating the on-going MDR application, for Class IIb devices, or   + FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or   Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan. |  |
| **Safety & product Standards:**  Bidder shall furnish the following documents:   * Valid ISO 13485 certificate. * Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety & regulatory standards:   + IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance   + IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests   + IEC 60601-2-49: Medical Electrical Equipment - Part 2-49: Particular Requirements for the Basic Safety and Essential Performance of Multifunction Patient Monitoring Equipment. |  |
| 1. **Dual fetal monitor (twins FHR)** | **Quantity, pcs:** |
| **Product Description**  Fetal monitoring provides graphic and numeric information on fetal heart rate (FHR) and maternal uterine activity (UA) to help clinical personnel assess fetal well-being.  **Electrical Requirements:**   * Power requirements according to Ukraine standards: 220 VAC ± 10%, 50 Hz. * Power cord with “F” type plug for medical devices. * Built-in rechargeable battery, allowing at least 3 hours of continuous operation.   **Technical specifications:**   * LCD or TFT screen of at least 6" * Monitoring fetal heart rate (FHR) and uterine contractions (UC). * Continuous monitoring of fetal heart rate (FHR) by ultrasonic pulsed doppler mode with autocorrelation. * Dual Ultrasonic Heart Rate channels for Twins Monitoring (FHR1, FHR2). Two (2) FHR ultrasound transducers included. * Automatic detection of transducers. * Signals overlap verification and separate twins FHR. * Ultrasound frequency: 1 MHz +/- 10%. * Monitoring of FHR in the range of at least 50-230 bpm, resolution 1 bpm, and accuracy of at least +/- 2 bpm. * Uterine contractions measured in the range of 0-100 relative units, resolution of 1 unit. Toco-transducer waterproof included. * TOCO. Measured in the range of 0-100 relative units, resolution of 1 unit. TOCO-transducer auto and manual zeroing. * Manual/automatic monitoring of fetal movements. Trace and marks. * Display shows at least FHR1, FHR2, UCs and alarms. * Remote switch for event marking. One (1) remote switch event marker with cable included. * Automatic self-test. * Integrated thermal printer with automatic and manual print-out modes.   + Print at least FHR1, FHR2, uterine contractions, fetal movement, and marked events.   + Print speeds 1, 2 and 3 cm/min   + Compatible with 150/152 mm thermal recording paper * Alarms for at least: FHR1 high/low, FHR2 high/low, low battery * All materials resistant to disinfection with hospital-grade products. * Indications and messages on the equipment in the language of the destination country (Ukraine) or at least in English as mandatory.   **Accessories:**   * Two (2) adjustable belts for ultrasound and toco transducer * Twenty-four (24) pieces of thermal recording paper * Ten (10) bottles of ultrasound gel. * Trolley for the Dual fetal monitor * Chassis and external components must be built of materials, and/or have a finish/coating resistant to corrosion and the application of disinfectants commonly used in healthcare premises.   *NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product during the first 12 months, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included and listed in the offer.* | 2 |
| **Documentation required:**  Bidder shall furnish the following documents:   * Manufacturer brochure or data sheet including at least all technical specifications required. * User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal. * Service manuals must be provided including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits. * List of all common spare parts and accessories with part numbers. * Manufacturer authorization Letter. * Commitment manufacturer letter including:   + installation and commissioning on site would be performed by the manufacturer or his representative in the country (according to the general requirements in the bid document under the clause “Installation and commissioning on site").   + at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause “Warranty").   + at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause “Post-sale Services").   + training on use, cleaning, and disinfecting for the healthcare staff, and basic maintenance for the technical staff, in Ukrainian and English language (according to the general requirements in the bid document under the clause “Training").   **NOTE: All the documents must be submitted in English and Ukrainian language as mandatory. The Russian language could be accepted as an exception to the Ukrainian language.** |  |
| **Regulatory approvals required:**  Bidder shall furnish **documentary evidence** to demonstrate that the good offered is approved according:   * Valid certificate or approval letter from national Ukrainian regulatory body, which confirms local registration of the product and permission to use it in medical practice. * Valid manufacturing licenses. * And at least one of the following regulatory approvals and certificates:   + European Certificate of Conformity (CE) with Regulation 2017/745 or Directive 93/42 EC and Agreement Letter signed with the NB demonstrating the on-going MDR application, for Class IIb devices, or   + FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or   Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan. |  |
| **Safety & product Standards:**  Bidder shall furnish the following documents:   * Valid ISO 13485 certificate. * Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety & regulatory standards:   + IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance   + IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests   + IEC 60601-2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment |  |

|  |  |
| --- | --- |
| 1. **High frequency electrosurgery generator** | **Quantity, pcs:** |
| **Product Description**  Electrosurgical generator using a high-frequency electrical current to cut tissue and control bleeding by causing coagulation.  **Electrical Requirements:**   * Power requirements according to Ukraine standards: 220 VAC ± 10%, 50 Hz. * Power cord with “F” type plug for medical devices.   **Technical specifications:**   * Delivery system: Monopolar and Bipolar. * For open surgeries and minimally invasive surgical treatments (laparoscopic or endoscopic). * Energy settings, at least:   + Monopolar * Cut (Maximum power output ≥ 250 Watts @ 250 Ω) * Coagulation (Maximum power output ≥ 120 Watts @ 200 Ω) * Blend (Maximum power output ≥ 150 Watts @ 150 Ω) * Bipolar * Coagulation (Maximum power output ≥ 80 Watts @ 50 Ω) * Working frequency ≥ 500 kHz * Power output activation   + Monopolar: Handswitch (handpiece) and footswitch   + Bipolar: Footswitch * With power-on self-test. * Instrument receptacles, at least:   + One (1) for monopolar handpiece   + One (1) bipolar instrument   + One (1) for footswitch   + One (1) for return electrode * Control panel:   + Touchscreen or membrane keys.   + On/Off switch.   + Power On indicator.   + With an audible activation indicator.   + LCD, TFT, LED display showing at least:     - * Setting power output (Monopolar and Bipolar).       * Return electrode contact quality indicator.   + Continuous monitoring, with visual and audible alarm at least for:     - * False contact of the return electrode       * Return electrode disconnected.       * Equipment failure. * Power output blocking in case of active electrode or neutral electrode contact failure. * Trolley for High Frequency Electrosurgical Unit. * Chassis and external components must be built of materials, and/or have a finish/coating resistant to corrosion and the application of disinfectants commonly used in healthcare premises.   **Accessories:**   * One (1) power supply cable. * Five (5) monopolar handles with activation buttons, reusable, sterilizable, with connection cable. * Five (5) set of monopolar electrodes, at least blade, needle, and ball type. * One (1) connection cable for the reusable return electrode. * One (1) reusable return electrode, sterilizable. * One hundred (100) disposable return electrode, with connection cable. * Footswitch(s) for monopolar and bipolar modes, with connecting cable. * Trolley with basket, made of steel with anti-corrosive epoxy coating, aluminum, AISI 304 stainless steel or higher quality material. With 4 castors and brake system.   *NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product during the first 12 months, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included and listed in the offer.* | 2 |
| **Documentation required:**  Bidder shall furnish the following documents:   * Manufacturer brochure or data sheet including at least all technical specifications required. * User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal. * Service manuals must be provided including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits. * List of all common spare parts and accessories with part numbers. * Manufacturer authorization Letter. * Commitment manufacturer letter including:   + installation and commissioning on site would be performed by the manufacturer or his representative in the country (according to the general requirements in the bid document under the clause “Installation and commissioning on site").   + at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause “Warranty").   + at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause “Post-sale Services").   + training on use, cleaning, and disinfecting for the healthcare staff, and basic maintenance for the technical staff, in Ukrainian and English language (according to the general requirements in the bid document under the clause “Training").   **NOTE: All the documents must be submitted in English and Ukrainian language as mandatory. The Russian language could be accepted as an exception to the Ukrainian language.** |  |
| **Regulatory approvals required:**  Bidder shall furnish **documentary evidence** to demonstrate that the good offered is approved according:   * Valid certificate or approval letter from national Ukrainian regulatory body, which confirms local registration of the product and permission to use it in medical practice. * Valid manufacturing licenses. * And at least one of the following regulatory approvals and certificates:   + European Certificate of Conformity (CE) with Regulation 2017/745 or Directive 93/42 EC and Agreement Letter signed with the NB demonstrating the on-going MDR application, for Class IIb devices, or   + FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or   Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan. |  |
| **Safety & product Standards:**  Bidder shall furnish the following documents:   * Valid ISO 13485 certificate. * Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety & regulatory standards:   + IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance   + IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests   + IEC 60601-2-2: Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories.   + ISO 10993-1 Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process |  |

|  |  |
| --- | --- |
| 1. **Infant radiant warmer** | **Quantity, pcs:** |
| **Product Description**  Infant radiant warmer used to provide thermal support for newborns in the delivery suite and for critically ill infants. For treatment and prevention of hypothermia  **Electrical Requirements:**   * Power requirements according to Ukraine standards: 220 VAC ± 10%, 50 Hz. * Power cord with “F” type plug for medical devices. * Rechargeable battery/batteries with autonomy of at least 1 hour. * Internal and integrated battery charging system.   **Technical specifications:**   * Infrared radiant heat source. * General system self-test. * Digital display of skin temperature, control temperature, heater power and alarms. * Temperature reading and control in degrees Celsius. * Parameter selection. * Preferably LCD screen * Operating modes: skin mode (servo control), manual mode and preferably pre-heating function. * Servo control of patient temperature in skin mode, using skin temperature sensor. Reusable skin temperature sensor included. * Temperature setting range of at least 35°C to 38°C. * Temperature resolution: 0.1 ºC * Skin temperature measurement accuracy: +/- 0.3 °C or better * Heater power control selectable in at least 3 levels between 0 and 100%, in manual mode. * Heated mattress, 30.0°C to 33.0°C * Integrated X-ray tray under the mattress. * Transparent acrylic panels on at least 3 sides, drop down and lockable. * Trendelenburg and reverse Trendelenburg positions, with a minimum angulation range of +/- 10°. * Audible and visual alarms, for at least:   + System failure.   + Electric power failure.   + Skin temperature sensor failure/disconnection.   + Variation of +/- 1 °C with respect to the established control temperature.   + Patient verification, after at least 15 minutes of operation in manual mode. * Observation lamp * At least one (1) tray for placing equipment. * At least one (1) integrated drawer or drawer, for storing accessories. * Handles for moving and positioning. * Integrated support for at least one oxygen bottle * Structure made at least of steel tube with anticorrosive finish in epoxy/electrostatic paint or higher quality. * Mounted on four (4) antistatic wheels, with locking mechanism, of at least 12.5 cm of diameter. * User interface on the equipment must be in English language as mandatory, and preferably also in Ukrainian language.   **Accessories:**   * Neonatal gel cushion for heated mattress, or mattress suitable for heated mattress. Cover of hypoallergenic and non-toxic material, waterproof and resistant to hospital-grade disinfection products. * Integrated IV pole. * Two (2) reusable skin temperature sensor, additional to that included in the device.   *NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product during the first 12 months, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included and listed in the offer.* | 4 |
| **Documentation required:**  Bidder shall furnish the following documents:   * Manufacturer brochure or data sheet including at least all technical specifications required. * User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal. * Service manuals must be provided including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits. * List of all common spare parts and accessories with part numbers. * Manufacturer authorization Letter. * Commitment manufacturer letter including:   + installation and commissioning on site would be performed by the manufacturer or his representative in the country (according to the general requirements in the bid document under the clause “Installation and commissioning on site").   + at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause “Warranty").   + at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause “Post-sale Services").   + training on use, cleaning, and disinfecting for the healthcare staff, and basic maintenance for the technical staff, in Ukrainian and English language (according to the general requirements in the bid document under the clause “Training").   **NOTE: All the documents must be submitted in English and Ukrainian language as mandatory. The Russian language could be accepted as an exception to the Ukrainian language.** |  |
| **Regulatory approvals required:**  Bidder shall furnish **documentary evidence** to demonstrate that the good offered is approved according:   * Valid certificate or approval letter from national Ukrainian regulatory body, which confirms local registration of the product and permission to use it in medical practice. * Valid manufacturing licenses. * And at least one of the following regulatory approvals and certificates:   + European Certificate of Conformity (CE) with Regulation 2017/745 or Directive 93/42 EC and Agreement Letter signed with the NB demonstrating the on-going MDR application, for Class IIb devices, or   + FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or   Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan. |  |
| **Safety & product Standards:**  Bidder shall furnish the following documents:   * Valid ISO 13485 certificate. * Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety & regulatory standards:   + IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance   + IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests   + IEC 60601-2-21: Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers. |  |
| 1. **Blood and IV fluid warmer** | **Quantity, pcs:** |
| **Product Description**  A device designed to warm homogeneously and continually the blood, blood products and intravenous fluids, to prevent hypothermia of the patient under treatment.  **Electrical Requirements:**   * Power requirements according to Ukraine standards: 220 VAC ± 10%, 50 Hz. * Power cord with “F” type plug for medical devices. * Built-in protection against defibrillator,   **Technical specifications:**   * Warmer type: In-line. * Compatible with universal, standard IV tube, O.D.: 3.5 to 5.0mm. * Dual channel. * Work regime: Continuous. * Microprocessor/Microcontroller controlled. * Control panel:   + Membrane keyboard or touch screen, with menu and options in English and/or Ukrainian. With user and equipment interaction complemented with pictorial resources.   + On/Off switch.   + LCD, TFT, LED Display showing at least:     - * Power On indicator.       * Setting temperature.       * Actual temperature.       * Operating/Warming time.   + Continuous monitoring, with visual and audible alarm at least for:     - * Low/ High temperature.       * Sensor malfunction.   + Automatic cut-off system. * Temperature control:   + Temperature setting: At least from 34°C or lower limit, to 40°C or higher limit.   + Temperature settings in steps of 0.1 °C or smaller.   + Independent temperature control per each channel. * Attachable to an IV Pole * Chassis and external components must be built of materials, and/or have a finish/coating resistant to corrosion and the application of disinfectants commonly used in healthcare premises.   **Accessories:**   * One (1) power supply cable. * Clamp for IV pole.   *NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product during the first 12 months, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included and listed in the offer.* | 2 |
| **Documentation required:**  Bidder shall furnish the following documents:   * Manufacturer brochure or data sheet including at least all technical specifications required. * User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal. * Service manuals must be provided including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits. * List of all common spare parts and accessories with part numbers. * Manufacturer authorization Letter. * Commitment manufacturer letter including:   + installation and commissioning on site would be performed by the manufacturer or his representative in the country (according to the general requirements in the bid document under the clause “Installation and commissioning on site").   + at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause “Warranty").   + at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause “Post-sale Services").   + training on use, cleaning, and disinfecting for the healthcare staff, and basic maintenance for the technical staff, in Ukrainian and English language (according to the general requirements in the bid document under the clause “Training").   **NOTE: All the documents must be submitted in English and Ukrainian language as mandatory. The Russian language could be accepted as an exception to the Ukrainian language.** |  |
| **Regulatory approvals required:**  Bidder shall furnish **documentary evidence** to demonstrate that the good offered is approved according:   * Valid certificate or approval letter from national Ukrainian regulatory body, which confirms local registration of the product and permission to use it in medical practice. * Valid manufacturing licenses. * And at least one of the following regulatory approvals and certificates:   + European Certificate of Conformity (CE) with Regulation 2017/745 or Directive 93/42 EC and Agreement Letter signed with the NB demonstrating the on-going MDR application, for Class IIb devices, or   + FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or   Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan. |  |
| **Safety & product Standards:**  Bidder shall furnish the following documents:   * Valid ISO 13485 certificate. * Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety & regulatory standards:   + IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance   + IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests   + ASTM F2172: Standard specification for blood/intravenous fluid irrigation warmer |  |
| 1. **Infant resuscitation radiant warmer** | **Quantity, pcs:** |
| **Product Description**  Mobile resuscitation table for neonatal patients equipped with a radiant warmer.  **Electrical Requirements:**   * Power requirements according to Ukraine standards: 220 VAC, 50 Hz. Power cord with plug F type for medical device. * Built-in rechargeable battery, allowing at least 1 hour of continuous operation.   **Technical specifications:**   * Infrared radiant heat source. * General system self-test. * Digital display of skin temperature, control temperature, heater power and alarms. * Temperature reading and control in degrees Celsius. * Parameter selection. * Preferably LCD screen with data trend * Operating modes: skin mode (servo), manual mode and preferably pre-heating function. * Servo control of patient temperature in skin mode, using skin temperature sensor. Reusable skin temperature sensor included. * Temperature setting range of at least 35°C to 38°C. * Temperature resolution: 0.1 ºC * Skin temperature measurement accuracy: +/- 0.3 °C or better * Heater power control selectable in at least 3 levels between 0 and 100%, in manual mode. * Integrated X-ray tray under the mattress. * Transparent acrylic panels on at least 3 sides, drop down and lockable. * Trendelenburg and reverse Trendelenburg positions, with a minimum angulation range of - 8, 5° to 10°. * Bed height adjustment. * Audible and visual alarms, for at least:   + System failure.   + Electric power failure.   + Skin temperature sensor failure/disconnection.   + Variation of +/- 1 °C with respect to the established control temperature.   + Patient verification, after at least 15 minutes of operation in manual mode. * Integrated phototherapy lamp, with the following characteristics:   + LED technology   + Emission wavelength within the range of 420 to 470 nm.   + Minimum irradiance 35 µwatts/cm2/nm, on the surface of the mattress.   + Therapy time indicator: integrated, operator resettable. * Gas input connections for both oxygen and compressed air from the hospital system gasses connection, and for gas cylinders with pressure regulators. With both options available. * Gas outlet for bag-valve-mask and for T-piece resuscitator. * PIP control. * Airway pressure indicator * Suction with adjustable vacuum level. On-off switch and vacuum level indicator. * Holder for secretion collection jar. Reusable collection jar included. * Preferably Air-Oxygen mixer * Observation lamp * At least one (1) tray for placing equipment. * At least one (1) integrated drawer or drawer, for storing accessories. * Handles for moving and positioning. * Support for At least one (1) cylinder type E or equivalent according to the standard of the destination country. * Structure made at least of steel tube with anticorrosive finish in epoxy/electrostatic paint or higher quality. * Mounted on four (4) antistatic wheels, with locking mechanism, of at least 12.5 cm of diameter. * Indications and messages on the equipment must be in English language as mandatory, and preferably also in Ukrainian language.   **Accessories:**   * Neonatal mattress. Thickness of at least 3 cm. Cover of hypoallergenic and non-toxic material, waterproof and resistant to hospital-grade disinfection products. * Integrated IV pole. * Two (2) reusable skin temperature sensors, additional to that included in the equipment. * Two (2) reusable phototherapy neonatal eye protectors. * One (1) hose with compatible connector for connection to the hospital medical oxygen network * One (1) hose with compatible connector for connection to the hospital medical compressed air network * One hundred (100) disposable neonatal resuscitation circuits complete with T-piece and PEEP valve. * Two (2) reusable aspiration bottles. In addition to what is included in the device   *NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product during the first 12 months, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included and listed in the offer.* | 1 |
| **Documentation required:**  Bidder shall furnish the following documents:   * Manufacturer brochure or data sheet including at least all technical specifications required. * User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal. * Service manuals must be provided including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits. * List of all common spare parts and accessories with part numbers. * Manufacturer authorization Letter. * Commitment manufacturer letter including:   + installation and commissioning on site would be performed by the manufacturer or his representative in the country (according to the general requirements in the bid document under the clause “Installation and commissioning on site").   + at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause “Warranty").   + at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause “Post-sale Services").   + training on use, cleaning, and disinfecting for the healthcare staff, and basic maintenance for the technical staff, in Ukrainian and English language (according to the general requirements in the bid document under the clause “Training").   **NOTE: All the documents must be submitted in English and Ukrainian language as mandatory. The Russian language could be accepted as an exception to the Ukrainian language.** |  |
| **Regulatory approvals required:**  Bidder shall furnish **documentary evidence** to demonstrate that the good offered is approved according:   * Valid certificate or approval letter from national Ukrainian regulatory body, which confirms local registration of the product and permission to use it in medical practice. * Valid manufacturing licenses. * And at least one of the following regulatory approvals and certificates:   + European Certificate of Conformity (CE) with Regulation 2017/745 or Directive 93/42 EC and Agreement Letter signed with the NB demonstrating the on-going MDR application, for Class IIb devices, or   + FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or   Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan. |  |
| **Safety & product Standards:**  Bidder shall furnish the following documents:   * Valid ISO 13485 certificate. * Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety & regulatory standards:   + IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance   + IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests   + IEC 60601-2-21: Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers. |  |
| 1. **Infant phototherapy unit** | **Quantity, pcs:** |
| **Product Description**  360° phototherapy LED cradle for treatment of jaundice in newborns. For use in healthcare institutions.  **Electrical Requirements:**   * Power requirements according to Ukraine standards: 220 VAC ± 10%, 50 Hz. * Power cord with “F” type plug for medical devices.   **Technical specifications:**   * Screen for control parameters and alarms. * Mounted on a trolley with four (4) antistatic castors, at least two of the castors with brakes. Structure made at least of steel tube with anticorrosive finish in epoxy/electrostatic paint or higher quality. * General system self-test. * LED technology lamp, arranged in 2 semi-cylindrical hoods. * 360° directional light irradiation * Radiation within the wavelength range of 440 – 470 nm * Minimum irradiance: ≥ 100 µW/cm2/nm * Air temperature monitoring inside the cradle * Skin temperature monitoring and display * Noise level ≤ 55 dB * Exposure time programming. Therapy time indicator * Observation windows on both sides * Sliding out bed * LEDs lifetime at least 50,000 hrs. * LEDs total usage time counter * Elevation the upper hood for cleaning and disinfecting the inside of the device. * Alarms for at least:   + High Skin temperature, adjustable between 33–39°C   + Low Skin temperature, adjustable between 31–37°C   + High Air temperature >38°C   + Low Air temperature <30°C   + Skin Probe disconnection/ failure   + Therapy Ended   + Power failure * One drawer at least * All surfaces antioxidant, resistant to corrosion of hospital grade disinfectants. * Indications and messages on the equipment must be in English language as mandatory, and preferably also in Ukrainian language.   **Accessories:**   * IV pole * Hammock or mattress translucent for therapeutic light * Three (3) reusable temperature skin sensor * Three (3) reusable phototherapy neonatal eye protectors, in three different sizes. * One (1) replacement air filter, if applicable   *NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product during the first 12 months, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included and listed in the offer.* | 1 |
| **Documentation required:**  Bidder shall furnish the following documents:   * Manufacturer brochure or data sheet including at least all technical specifications required. * User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal. * Service manuals must be provided including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits. * List of all common spare parts and accessories with part numbers. * Manufacturer authorization Letter. * Commitment manufacturer letter including:   + installation and commissioning on site would be performed by the manufacturer or his representative in the country (according to the general requirements in the bid document under the clause “Installation and commissioning on site").   + at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause “Warranty").   + at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause “Post-sale Services").   + training on use, cleaning, and disinfecting for the healthcare staff, and basic maintenance for the technical staff, in Ukrainian and English language (according to the general requirements in the bid document under the clause “Training").   **NOTE: All the documents must be submitted in English and Ukrainian language as mandatory. The Russian language could be accepted as an exception to the Ukrainian language.** |  |
| **Regulatory approvals required:**  Bidder shall furnish **documentary evidence** to demonstrate that the good offered is approved according:   * Valid certificate or approval letter from national Ukrainian regulatory body, which confirms local registration of the product and permission to use it in medical practice. * Valid manufacturing licenses. * And at least one of the following regulatory approvals and certificates:   + European Certificate of Conformity (CE) with Regulation 2017/745 or Directive 93/42 EC and Agreement Letter signed with the NB demonstrating the on-going MDR application, for Class IIb devices, or   + FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan. |  |
| **Safety & product Standards:**  Bidder shall furnish the following documents:   * Valid ISO 13485 certificate. * Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety & regulatory standards:   + IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance   + IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests   + IEC 60601-2-21: Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers.   + IEC 60601-2-50 Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment |  |
| 1. **Portable 12-lead electrocardiograph** | **Quantity, pcs:** |
| **Product Description**  Medical device for recording the changes of electrical potential occurring during the heartbeat used especially in diagnosing abnormalities of heart action.  **Electrical Requirements:**   * Power requirements according to Ukraine standards: 220 VAC ± 10%, 50 Hz. * Power cord with “F” type plug for medical devices. * Rechargeable battery/batteries with autonomy of at least 10 minutes of continuous use. * Internal and integrated battery charging system. * Built-in protection against defibrillators.   **Technical specifications:**   * Electrocardiograph, simultaneously 12 leads acquisition, capable of monitoring and generating a record of the following leads: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5 and V6. * For adult, pediatric, and newborn patients. * Operation:   + Manual.   + Automatic. * Control panel:   + Membrane keyboard or touch screen, with menu and options in English and/or Ukrainian. With user and equipment interaction complemented with pictorial resources.   + On/Off switch.   + LCD, TFT, LED Display showing at least:     - * Power On indicator.       * Patient ID.       * Waveforms.       * Derivation.       * Battery charge level indicator.       * Electrode disconnection alarm. * Performance:   + Filter settings, at least:     - * Power line filters (AC): Off, 50, 60Hz       * EMG: Off, 25 to 150Hz       * Baseline drift: Off, 0.01 to 0.6Hz   + Sensitivity: Auto, 5, 10, 20, 40mm/mV   + CMRR: ≥ 130dB   + Input impedance: ≥ 60 MΩ @ 10 Hz   + Heart rate range: 30 to 350 bpm   + Pacemaker detection * Selectable printing/displaying formats, at least:   + Plain: 3×4, 6×2, 12×1   + Rhythm: 3×4+1R, 3×4+3R, 6×2+1R, 6×2+3R   + Printing speed: 5, 6.25, 10, 12.5, 25, 50mm/s * With thermal array printer:   + Z-fold paper type.   + Printing information, at least:     - * Date and time.       * Patient ID.       * Waveforms.       * Derivation.       * Print speed. * With data storage capabilities. * Chassis and external components must be built of materials, and/or have a finish/coating resistant to corrosion and the application of disinfectants commonly used in healthcare premises.   **Accessories:**   * One (1) power supply cable. * One (1) reusable patient cable for ten (10) electrodes [twelve (12) leads]. * One (1) set of six (6) units of suction chest electrodes. * One (1) set of four (4) units of clamp-type electrodes for limbs. * Twenty-five (25) sets of electrodes for newborns (premature newborns), disposable. * Twenty (20) reams of thermosensitive and millimeter paper for ECG. * Twenty (20) Tubes of electroconductive gel of at least 250ml each one.   *NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product during the first 12 months, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included and listed in the offer. Available of thermosensitive paper of the appropriate size and standard in Ukrainian market.* | 1 |
| **Documentation required:**  Bidder shall furnish the following documents:   * Manufacturer brochure or data sheet including at least all technical specifications required. * User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal. * Service manuals must be provided including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits. * List of all common spare parts and accessories with part numbers. * Manufacturer authorization Letter. * Commitment manufacturer letter including:   + installation and commissioning on site would be performed by the manufacturer or his representative in the country (according to the general requirements in the bid document under the clause “Installation and commissioning on site").   + at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause “Warranty").   + at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause “Post-sale Services").   + training on use, cleaning, and disinfecting for the healthcare staff, and basic maintenance for the technical staff, in Ukrainian and English language (according to the general requirements in the bid document under the clause “Training").   **NOTE: All the documents must be submitted in English and Ukrainian language as mandatory. The Russian language could be accepted as an exception to the Ukrainian language.** |  |
| **Regulatory approvals required:**  Bidder shall furnish **documentary evidence** to demonstrate that the good offered is approved according:   * Valid certificate or approval letter from national Ukrainian regulatory body, which confirms local registration of the product and permission to use it in medical practice. * Valid manufacturing licenses. * And at least one of the following regulatory approvals and certificates:   + European Certificate of Conformity (CE) with Regulation 2017/745 or Directive 93/42 EC and Agreement Letter signed with the NB demonstrating the on-going MDR application, for Class IIa devices, or   + FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or   Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan. |  |
| **Safety & product Standards:**  Bidder shall furnish the following documents:   * Valid ISO 13485 certificate. * Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety & regulatory standards:   + IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance   + IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests   + IEC 60601-2-25: Medical Electrical Equipment- Part 2-25: Particular Requirements For The Basic Safety And Essential Performance Of Electrocardiographs. (Cardiovascular) |  |

|  |  |
| --- | --- |
| 1. **Surgical aspirator** | **Quantity, pcs:** |
| **Product Description**  Medical devices to generate and maintain a controlled source of vacuum to remove body fluids from wounds and cavities during surgical procedures in adult and pediatric patients.  **Electrical Requirements:**   * Power requirements according to Ukraine standards: 220 VAC ± 10%, 50 Hz. * Power cord with “F” type plug for medical devices.   **Technical specifications:**   * Electric suction pump, oil-less and maintenance free, rotary, piston, or diaphragm type. * For continuous work. * Suction flow: ≥ 45 LPM at maximum suction. * Adjustable vacuum: From -150 or lower vacuum level to - 630 mmHg or higher vacuum level. * Control panel:   + On/Off switch.   + Power On indicator.   + Control knob to select suction limit.   + Precision vacuum gauge for the entire vacuum range generated. * Suction containers (bottles):   + Two (2) Reusable containers.   + Made of polycarbonate or polysulfone.   + Volumetric capacity: ≥ 2.5 liters each one.   + With visible measurement scale, graduated in ml or cc.   + Autoclavable, saturated steam sterilizable.   + Thread type lid, with sealing gasket and overflow safety device. * With an antibacterial and hydrophobic filter in the connection between the electric suction pump and the first container (bottle). * Mobile equipment, with four (4) caster wheels for easy movement, must support all the components of the equipment (Pump, Containers (Bottles), Filters, etc.). * Chassis and external components must be built of materials, and/or have a finish/coating resistant to corrosion and the application of disinfectants commonly used in healthcare premises.   **Accessories:**   * One (1) power supply cable. * One (1) spare reusable polycarbonate or polysulfone container (bottle). * Fifty (50) disposable antibacterial and hydrophobic filters.   *NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product during the first 12 months, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included and listed in the offer.* | 3 |
| **Documentation required:**  Bidder shall furnish the following documents:   * Manufacturer brochure or data sheet including at least all technical specifications required. * User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal. * Service manuals must be provided including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits. * List of all common spare parts and accessories with part numbers. * Manufacturer authorization Letter. * Commitment manufacturer letter including:   + installation and commissioning on site would be performed by the manufacturer or his representative in the country (according to the general requirements in the bid document under the clause “Installation and commissioning on site").   + at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause “Warranty").   + at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause “Post-sale Services").   + training on use, cleaning, and disinfecting for the healthcare staff, and basic maintenance for the technical staff, in Ukrainian and English language (according to the general requirements in the bid document under the clause “Training").   **NOTE: All the documents must be submitted in English and Ukrainian language as mandatory. The Russian language could be accepted as an exception to the Ukrainian language.** |  |
| **Regulatory approvals required:**  Bidder shall furnish **documentary evidence** to demonstrate that the good offered is approved according:   * Valid certificate or approval letter from national Ukrainian regulatory body, which confirms local registration of the product and permission to use it in medical practice. * Valid manufacturing licenses. * And at least one of the following regulatory approvals and certificates:   + European Certificate of Conformity (CE) with Regulation 2017/745 or Directive 93/42 EC and Agreement Letter signed with the NB demonstrating the on-going MDR application, for Class IIa devices, or   + FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or   Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan. |  |
| **Safety & product Standards:**  Bidder shall furnish the following documents:   * Valid ISO 13485 certificate. * Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety & regulatory standards:   + IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance   + IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests   + ISO 10079-1: Medical suction equipment. Part 1: Electrically powered suction equipment |  |
| 1. **Flexible Video Laryngoscope** | **Quantity, pcs:** |
| **Product Description**  The video laryngoscope is a device designed for endotracheal intubation of patients who require assistance in the delivery of oxygen due to surgical or emergency events, especially for difficult airways.  **Electrical Requirements:**   * Power requirements according to Ukraine standards: 220 VAC ± 10%, 50 Hz. * Power cord with “F” type plug for medical devices. * Rechargeable battery/batteries with autonomy of at least 240 minutes of continuous use. * Internal and integrated battery charging system.   **Technical specifications:**   * Portable tracheal intubation system, video assisted. * Provides a real-time view of the airways enabling quick intubation of adult, pediatric, and neonatal patients. * Monitor:   + LCD, TFT, LED display.   + Display size at least 3.0”   + Integrated in a single piece with the handle or connectable.   + Battery indicator status. * Video camera with CMOS (Complementary Metal Oxide Semiconductor) or CCD (Charge Coupled Device) technology. * LED Light Source. * Storing capabilities: ≥ 16GB * Flexible tube set for complex tracheal intubation, with the following characteristics:   + Working length: ≥ 60cm.   + Insertion tube: ≤ 4.0mm.   + Field of view: 100°.   + Depth of view: ≥ 5cm.   + Range of bending:     - Up: ≥ 160°     - Down: ≥ 130° * Chassis and external components must be built of materials, and/or have a finish/coating resistant to corrosion and the application of disinfectants commonly used in healthcare premises.   **Accessories:**   * One (1) Carrying case.   *NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product during the first 12 months, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included and listed in the offer.* | 1 |
| **Documentation required:**  Bidder shall furnish the following documents:   * Manufacturer brochure or data sheet including at least all technical specifications required. * User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal. * Service manuals must be provided including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits. * List of all common spare parts and accessories with part numbers. * Manufacturer authorization Letter. * Commitment manufacturer letter including:   + installation and commissioning on site would be performed by the manufacturer or his representative in the country (according to the general requirements in the bid document under the clause “Installation and commissioning on site").   + at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause “Warranty").   + at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause “Post-sale Services").   + training on use, cleaning, and disinfecting for the healthcare staff, and basic maintenance for the technical staff, in Ukrainian and English language (according to the general requirements in the bid document under the clause “Training").   **NOTE: All the documents must be submitted in English and Ukrainian language as mandatory. The Russian language could be accepted as an exception to the Ukrainian language.** |  |
| **Regulatory approvals required:**  Bidder shall furnish **documentary evidence** to demonstrate that the good offered is approved according:   * Valid certificate or approval letter from national Ukrainian regulatory body, which confirms local registration of the product and permission to use it in medical practice. * Valid manufacturing licenses. * And at least one of the following regulatory approvals and certificates:   + European Certificate of Conformity (CE) with Regulation 2017/745 or Directive 93/42 EC and Agreement Letter signed with the NB demonstrating the on-going MDR application, for Class IIa devices, or   + FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or   Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan. |  |
| **Safety & product Standards:**  Bidder shall furnish the following documents:   * Valid ISO 13485 certificate. * Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety & regulatory standards:   + IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance   + IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests   + IEC 60601-1-12: Medical Electrical Equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the emergency medical services environment. |  |
| 1. **Portable medical aspirator for neonatal use** | **Quantity, pcs:** |
| **Product Description**  Portable medical device to generate and maintain a controlled source of vacuum to remove body fluids from wounds and cavities during medical procedures in neonate inpatient care and outpatient transportation.  **Electrical Requirements:**   * Power requirements according to Ukraine standards: 220 VAC ± 10%, 50 Hz. * Power cord with “F” type plug for medical devices. * Rechargeable battery/batteries with autonomy of at least 45 minutes of continuous use. * Internal and integrated battery charging system. * Functional with 12 VDC (available in ambulances).   **Technical specifications:**   * Electric suction pump, oil-less and maintenance free, rotary, piston or diaphragm type. * For continuous work. * Suction flow: ≥ 5 LPM at maximum suction. * Adjustable vacuum: From -10 or lower vacuum level to - 150 mmHg. * Control panel:   + On/Off switch.   + Power On indicator.   + Control knob to select suction limit.   + Precision vacuum gauge for the entire vacuum range generated. * Suction containers (bottles):   + One (1) Reusable container.   + Made of polycarbonate or polysulfone.   + Volumetric capacity: ≥ 1.0 liter.   + With visible measurement scale, graduated in ml or cc.   + Autoclavable, saturated steam sterilizable.   + Thread type lid, with sealing gasket and overflow safety device. * With an antibacterial and hydrophobic filter in the connection between the electric suction pump and the first container (bottle). * Weight: ≤ 5 kg * Portable equipment, with handle. * Chassis and external components must be built of materials, and/or have a finish/coating resistant to corrosion and the application of disinfectants commonly used in healthcare premises.   **Accessories:**   * One (1) power supply cable. * One (1) spare reusable polycarbonate or polysulfone container (bottle). * Twenty-five (25) disposable antibacterial and hydrophobic filters.   *NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product during the first 12 months, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included and listed in the offer.* | 2 |
| **Documentation required:**  Bidder shall furnish the following documents:   * Manufacturer brochure or data sheet including at least all technical specifications required. * User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal. * Service manuals must be provided including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits. * List of all common spare parts and accessories with part numbers. * Manufacturer authorization Letter. * Commitment manufacturer letter including:   + installation and commissioning on site would be performed by the manufacturer or his representative in the country (according to the general requirements in the bid document under the clause “Installation and commissioning on site").   + at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause “Warranty").   + at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause “Post-sale Services").   + training on use, cleaning, and disinfecting for the healthcare staff, and basic maintenance for the technical staff, in Ukrainian and English language (according to the general requirements in the bid document under the clause “Training").   **NOTE: All the documents must be submitted in English and Ukrainian language as mandatory. The Russian language could be accepted as an exception to the Ukrainian language.** |  |
| **Regulatory approvals required:**  Bidder shall furnish **documentary evidence** to demonstrate that the good offered is approved according:   * Valid certificate or approval letter from national Ukrainian regulatory body, which confirms local registration of the product and permission to use it in medical practice. * Valid manufacturing licenses. * And at least one of the following regulatory approvals and certificates:   + European Certificate of Conformity (CE) with Regulation 2017/745 or Directive 93/42 EC and Agreement Letter signed with the NB demonstrating the on-going MDR application, for Class IIa devices, or   + FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or   Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan. |  |
| **Safety & product Standards:**  Bidder shall furnish the following documents:   * Valid ISO 13485 certificate. * Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety & regulatory standards:   + IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance   + IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests   + ISO 10079-1: Medical suction equipment. Part 1: Electrically powered suction equipment |  |

|  |  |
| --- | --- |
| 1. **Birthing bed** | **Quantity, pcs:** |
| **Product Description**  Adjustable bed designed to support a woman's body in an appropriate position during labor and delivery and in other examination/treatment procedures related to pregnancy. Electrically controlled.  **Electrical Requirements:**   * Power requirements according to Ukraine standards: 220 VAC ± 10%, 50 Hz. * Power cord with “F” type plug for medical devices. * Built-in rechargeable batteries with autonomy for at least 1 hour.   **Technical specifications:**   * Operation: electric for at least adjustment of the bed height, inclination of the backrest section, Trendelenburg and Anti-Trendelenburg positioning. * Motors protection at least IPX4. * Wired hand control unit for bed movements, with graphic indications, included. Additionally, a control panel integrated into the side boards is desirable. * Number of sections: at least 3 sections (backrest, seat, and footrest). * Structure made at least of steel tube with anticorrosive finish in epoxy/electrostatic paint or higher quality. * Stainless steel side rails for accessory placement. * Folding side restraints on each side of the bed, made of Polypropylene, ABS, or similar material, resistant to hospital-grade disinfection products. * Headboard made of Polypropylene, ABS, or similar material, resistant to hospital disinfectants. Removable. * Mattress: polyurethane foam, in sections that match layout of table sections. Cover of hypoallergenic and non-toxic material, waterproof and resistant to hospital-grade disinfection products. * Seat section with gynecological perineal cut. * Holes for IV holders on both sides of the bed * Removable or folding footrest section allowing lithotomy position. * Mounted on four (4) antistatic wheels, with brakes on all of them, of at least 12.5 cm of diameter. * Load weight capacity min.: 180 kg. * Width: at least 90 cm * Length: at least 200 cm * All materials resistant to hospital-use disinfectants * Movements:   + Adjustable height. Lower position at least 66 cm from floor level.   + Adjustable backrest up to 70°.   + Trendelenburg and Anti-Trendelenburg positioning, at least 12°   + Preferably Up-folding of seat plate at least 15°   + Able to reach chair position.   + Release mechanism to CPR position.   **Accessories:**   * Removable or folding footrest section. * Two (2) leg rest Goepel type, padded, removable or foldable, adjustable in height, and in all planes. With the same upholstery as the bed, and with sliding grip holder * Two hand grips, adjustable on each side of the table. With sliding grip holder * Removable stainless steel fluid bowl. * IV pole, adjustable on each side of the table. * Hand control: If the bed does not have an integrated control panel, a wired hand control must be provided in addition to the one included with the device.   *NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product during the first 12 months, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included and listed in the offer.* | 1 |
| **Documentation required:**  Bidder shall furnish the following documents:   * Manufacturer brochure or data sheet including at least all technical specifications required. * User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal. * Service manuals must be provided including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits. * List of all common spare parts and accessories with part numbers. * Manufacturer authorization Letter. * Commitment manufacturer letter including:   + installation and commissioning on site would be performed by the manufacturer or his representative in the country (according to the general requirements in the bid document under the clause “Installation and commissioning on site").   + at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause “Warranty").   + at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause “Post-sale Services").   + training on use, cleaning, and disinfecting for the healthcare staff, and basic maintenance for the technical staff, in Ukrainian and English language (according to the general requirements in the bid document under the clause “Training").   **NOTE: All the documents must be submitted in English and Ukrainian language as mandatory. The Russian language could be accepted as an exception to the Ukrainian language.** |  |
| **Regulatory approvals required:**  Bidder shall furnish **documentary evidence** to demonstrate that the good offered is approved according:   * Valid certificate or approval letter from national Ukrainian regulatory body, which confirms local registration of the product and permission to use it in medical practice. * Valid manufacturing licenses. * And at least one of the following regulatory approvals and certificates:   + Declaration of Conformity (DoC) according with regulation 2017/745 for Medical Devices Class I or,   + FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or   Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan. |  |
| **Safety & product Standards:**  Bidder shall furnish the following documents:   * Valid ISO 13485 certificate. * Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety & regulatory standards:   + IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance   + IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests   + IEC 60601-2-52: Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds |  |
| 1. **Surgical table** | **Quantity, pcs:** |
| **Product Description**  Table on which a patient lies during a surgical procedure, to keep the patient in place while the surgical team operates, allowing multiple movements and position for easier access to the surgical site.  **Electrical Requirements:**   * Power requirements according to Ukraine standards: 220 VAC ± 10%, 50 Hz. * Power cord with “F” type plug for medical devices.   **Technical specifications:**   * It should allow accessory configurations for different surgical specialties. * Movements of the table by means of electric, hydraulic, pneumatic actuators. * The operating surface divided into 5 segments:   + Head section.   + Backrest section.   + Pelvic section (seat).   + Two (2) Individual leg sections (Left/Right). * Adjustments:   + Height adjustment.   + Lateral inclination on both sides (≥ ± 20°).   + Trendelemburg and anti-trendelemburg (≥ ± 15°).   + Back section adjustment (Up: ≥ +70°; Down: ≥ - 5°).   + Leg section adjustment.   + Head section adjustment. * Selection of movements through hand control:   + Height adjustment.   + Lateral inclination on both sides.   + Trendelemburg and anti-trendelemburg.   + Leg section adjustment. * Hand control with clip for placement on the accessory rail. * Maximum load capacity of at least 180 kg (396 lbs). * Dimensions:   + Table length: At least 210 cm ± 5 cm, considering head section.   + Bed/surface width: At least 55 cm ± 5 cm, without the side rails for accessories. * Materials:   + Bed/surface, radiolucent in all sections, except pelvic section (seat).   + Surface structure, column in stainless steel or better quality.   + Table base is covered in stainless steel.   + Side rails (left and right) made of stainless steel, to support accessories. * With at least four (4) wheels, with a locking system (brakes). * Chassis and external components must be built of materials, and/or have a finish/coating resistant to corrosion and the application of disinfectants commonly used in healthcare premises.   **Accessories:**   * One (1) power supply cable. * One mattress, without seams for each section. * One anesthesia screen arm. * One IV pole. * One pair of padded armrests, with radial support strap each. * One set of body restraint straps. * Complete set of brackets/clamps enough to support all the listed accessories on the table's accessory rails.   *NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product during the first 12 months, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included and listed in the offer.* | 2 |
| **Documentation required:**  Bidder shall furnish the following documents:   * Manufacturer brochure or data sheet including at least all technical specifications required. * User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal. * Service manuals must be provided including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits. * List of all common spare parts and accessories with part numbers. * Manufacturer authorization Letter. * Commitment manufacturer letter including:   + installation and commissioning on site would be performed by the manufacturer or his representative in the country (according to the general requirements in the bid document under the clause “Installation and commissioning on site").   + at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause “Warranty").   + at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause “Post-sale Services").   + training on use, cleaning, and disinfecting for the healthcare staff, and basic maintenance for the technical staff, in Ukrainian and English language (according to the general requirements in the bid document under the clause “Training").   **NOTE: All the documents must be submitted in English and Ukrainian language as mandatory. The Russian language could be accepted as an exception to the Ukrainian language.** |  |
| **Regulatory approvals required:**  Bidder shall furnish **documentary evidence** to demonstrate that the good offered is approved according:   * Valid certificate or approval letter from national Ukrainian regulatory body, which confirms local registration of the product and permission to use it in medical practice. * Valid manufacturing licenses. * And at least one of the following regulatory approvals and certificates:   + Declaration of Conformity (DoC) according with regulation 2017/745 for Medical Devices Class I or,   + FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or   Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan. |  |
| **Safety & product Standards:**  Bidder shall furnish the following documents:   * Valid ISO 13485 certificate. * Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety & regulatory standards:   + IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance   + IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests   + IEC 60601-2-52: Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds |  |
| 1. **Newborn crib with heating** | **Quantity, pcs:** |
| **Product Description**  Crib with warmer system based on heated mattress system to assist babies maintaining the appropriate body temperature.  **Electrical Requirements:**   * Power requirements according to Ukraine standards: 220 VAC ± 10%, 50 Hz. * Power cord with “F” type plug for medical devices.   **Technical specifications:**   * Cot with heated mattress. * Heating system consisting of at least: control unit, heating element, gel mattress and cover. * Heating system portable, capable of being used in any cot. * Non-water based warming system. * Control unit:   + Auto-test   + Indicator screen of current and set temperatures.   + Temperature setting: at least 34°С - 38°С, increment at least 0.5°C.   + Continuous operation   + Audible and visual alarms   + Mechanism to adjust to the crib, support, hook to hang or similar.   + Temperature sensor in the mattress or heating element   + Uniform temperature distribution in the mattress   + Connection cable included. * Gel pad mattress. Leakproof, Latex-free, non-allergenic * Reusable cover to house the gel pad and heating element, removable. Material hypoallergenic, non-toxic, fire retardant, waterproof and resistant to hospital-grade disinfection products. Included * Dimensions of the mattress according to the size of the bassinet. At least: 60 cm x 35 cm * Cot:   + Fully transparent bassinet   + Approximate Bassinet dimensions: 62 cm x 40 cm x 22 cm (h)   + Material of bassinet: transparent acrylic, or similar, nontoxic. Resistant to hospital-grade disinfectant products   + Holes in the cradle that allow the control unit cables to pass through, avoiding being routed over the top.   + Mounted on a trolley with four (4) antistatic castors, at least two of the castors with brakes.   + Structure made at least of steel tube with anticorrosive finish in epoxy/electrostatic paint or higher quality.   + Push handles. * All materials resistant to disinfection with hospital-grade products.   **Accessories:**   * Three (3) reusable cover to house the gel pad and heating element, removable. Material hypoallergenic, non-toxic, fire retardant, waterproof and resistant to hospital-grade disinfection products. In addition to that included with the device   *NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product during the first 12 months, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included and listed in the offer.* | 4 |
| **Documentation required:**  Bidder shall furnish the following documents:   * Manufacturer brochure or data sheet including at least all technical specifications required. * User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal. * Service manuals must be provided including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits. * List of all common spare parts and accessories with part numbers. * Manufacturer authorization Letter. * Commitment manufacturer letter including:   + installation and commissioning on site would be performed by the manufacturer or his representative in the country (according to the general requirements in the bid document under the clause “Installation and commissioning on site").   + at least one (1) year of full onsite warranty (according to the general requirements in the bid document under the clause “Warranty").   + at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause “Post-sale Services").   + training on use, cleaning, and disinfecting for the healthcare staff, and basic maintenance for the technical staff, in Ukrainian and English language (according to the general requirements in the bid document under the clause “Training").   **NOTE: All the documents must be submitted in English and Ukrainian language as mandatory. The Russian language could be accepted as an exception to the Ukrainian language.** |  |
| **Regulatory approvals required:**  Bidder shall furnish **documentary evidence** to demonstrate that the good offered is approved according:   * Valid certificate or approval letter from national Ukrainian regulatory body, which confirms local registration of the product and permission to use it in medical practice. * Valid manufacturing licenses. * And at least one of the following regulatory approvals and certificates:   + Declaration of Conformity (DoC) according to regulation 2017/745 for Medical Devices Class I or,   + FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or   Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan. |  |
| **Safety & product Standards:**  Bidder shall furnish the following documents:   * Valid ISO 9001 certificate, preferably ISO 13485 certificate. * Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety & regulatory standards:   + IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance   + IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.   + IEC 80601-2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use. |  |
| 1. **Hospital bed** | **Quantity, pcs:** |
| **Product Description**  Patient bed for rest/sleep in hospitals, electrically operated, on four castors, including a mattress.  **Electrical Requirements:**   * Power requirements according to Ukraine standards: 220 VAC ± 10%, 50 Hz. * Power cord with “F” type plug for medical devices.   **Technical specifications:**   * Operation: electric for at least adjustment of the bed height, inclination of the backrest section, the middle section (knees) and the leg section. * Motors protection at least IPX4. * Wired hand control unit for bed movements, with graphic indications for movements, included. * Number of sections: at least 4 sections. * Structure made at least of steel tube with anticorrosive finish in epoxy/electrostatic paint or higher quality. * Folding side restraints on each side of the bed, made of Polypropylene, ABS, or similar, or aluminum bar type. Resistant to hospital-grade disinfection products. * Headboard and footboard made of Polypropylene, ABS, or similar, resistant to hospital disinfectants. Removable. * Holes on each side of the bed to install an IV stand. * Mounted on four (4) antistatic wheels, with brakes on all of them, of at least 12.5 cm of diameter. * Load weight capacity min.: 200 kg. * Rest surface width: at least 90 cm. * Rest surface length: at least 199 cm. * All materials resistant to hospital-use disinfectants * Movements:   + Height adjustment range, at least 50-67 cm.   + Adjustable backrest up to 90°.   + Adjustment of the knee section, at least 45°   **Accessories:**   * Mattress: polyurethane foam. Cover of hypoallergenic and non-toxic material, waterproof and resistant to hospital-grade disinfection products. * Polyurethane foam pillow   *NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product during the first 12 months, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included and listed in the offer.* | 10 |
| **Documentation required:**  Bidder shall furnish the following documents:   * Manufacturer brochure or data sheet including at least all technical specifications required. * User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal. * Service manuals must be provided including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits. * List of all common spare parts and accessories with part numbers. * Manufacturer authorization Letter. * Commitment manufacturer letter including:   + installation and commissioning on site would be performed by the manufacturer or his representative in the country (according to the general requirements in the bid document under the clause “Installation and commissioning on site").   + at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause “Warranty").   + at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause “Post-sale Services").   + training on use, cleaning, and disinfecting for the healthcare staff, and basic maintenance for the technical staff, in Ukrainian and English language (according to the general requirements in the bid document under the clause “Training").   **NOTE: All the documents must be submitted in English and Ukrainian language as mandatory. The Russian language could be accepted as an exception to the Ukrainian language.** |  |
| **Regulatory approvals required:**  Bidder shall furnish **documentary evidence** to demonstrate that the good offered is approved according:   * Valid certificate or approval letter from national Ukrainian regulatory body, which confirms local registration of the product and permission to use it in medical practice. * Valid manufacturing licenses. * And at least one of the following regulatory approvals and certificates:   + Declaration of Conformity (DoC) according with regulation 2017/745 for Medical Devices Class I or,   + FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or   Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan. |  |
| **Safety & product Standards:**  Bidder shall furnish the following documents:   * Valid ISO 9001 certificate, preferably ISO 13485 certificate. * Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety & regulatory standards:   + IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance   + IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests   + IEC 60601-2-52: Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds |  |
| 1. **Surgical mobile lamp** | **Quantity, pcs:** |
| **Product Description**  Mobile surgical lamp designed to provide a specialized source of light during a minor surgical intervention, movable allowing the optimization of visibility of the surgeon, making it easier the reposition if it’s necessary.  **Electrical Requirements:**   * Power requirements according to Ukraine standards: 220 VAC ± 10%, 50 Hz. * Power cord with “F” type plug for medical devices.   **Technical specifications:**   * Mobile system, mounted on a base stand. * Base with at least four (4) anti-static swivel castors. A minimum of two (2) castors with brakes. * LED technology. * Multiple LEDs ≥ 24 Units. * LED lifespan: at least 50,000 hrs. * Maximum center illumination level, at 1m distance: 120,000 lux. Without shadows. * Head/Dome diameter: 400 mm ± 10%. * Color temperature: between 4,000 and 5,600 K. * Color rendering index: at least 95. * Control with On/Off control and light intensity. * Intensity adjustment: at least 3 levels. * Chassis and external components must be built of materials, and/or have a finish/coating resistant to corrosion and the application of disinfectants commonly used in healthcare premises.   **Movements:**   * Head/Dome, at least:   + Horizontal/Longitudinal axle: ± 180° * Arm, at least:   + Transversal axle: At least 75°   **Accessories:**   * One (1) power supply cable. * Two hundred (200) disposable sterile handle covers. * Two (2) removable and autoclavable handles, sterilized with saturated steam under pressure @ 134 °C or higher temperature.   *NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product during the first 12 months, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included and listed in the offer.* | 4 |
| **Documentation required:**  Bidder shall furnish the following documents:   * Manufacturer brochure or data sheet including at least all technical specifications required. * User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal. * Service manuals must be provided including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits. * List of all common spare parts and accessories with part numbers. * Manufacturer authorization Letter. * Commitment manufacturer letter including:   + installation and commissioning on site would be performed by the manufacturer or his representative in the country (according to the general requirements in the bid document under the clause “Installation and commissioning on site").   + at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause “Warranty").   + at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause “Post-sale Services").   + training on use, cleaning, and disinfecting for the healthcare staff, and basic maintenance for the technical staff, in Ukrainian and English language (according to the general requirements in the bid document under the clause “Training").   **NOTE: All the documents must be submitted in English and Ukrainian language as mandatory. The Russian language could be accepted as an exception to the Ukrainian language.** |  |
| **Regulatory approvals required:**  Bidder shall furnish **documentary evidence** to demonstrate that the good offered is approved according:   * Valid certificate or approval letter from national Ukrainian regulatory body, which confirms local registration of the product and permission to use it in medical practice. * Valid manufacturing licenses. * And at least one of the following regulatory approvals and certificates:   + Declaration of Conformity (DoC) according with regulation 2017/745 for Medical Devices Class I or,   + FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or   Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan. |  |
| **Safety & product Standards:**  Bidder shall furnish the following documents:   * Valid ISO 13485 certificate. * Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety & regulatory standards:   + IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance   + IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests   + IEC 60601-2-41: Medical Electrical Equipment, Part 2-41: Particular Requirements for the Safety of Surgical Luminaires and Luminaires for Diagnosis. |  |
| 1. **Surgical mobile lamp with battery** | **Quantity, pcs:** |
| **Product Description**  Mobile surgical lamp designed to provide a specialized source of light during a minor surgical intervention, movable allowing the optimization of visibility of the surgeon, making it easier the reposition if it’s necessary.  **Electrical Requirements:**   * Power requirements according to Ukraine standards: 220 VAC ± 10%, 50 Hz. * Power cord with “F” type plug for medical devices. * Rechargeable battery/batteries with autonomy of at least 10 minutes of continuous use at maximum intensity. * Internal and integrated battery charging system.   **Technical specifications:**   * Mobile system, mounted on a base stand. * Base with at least four (4) anti-static swivel castors. A minimum of two (2) castors with brakes. * LED technology. * Multiple LEDs ≥ 72 Units. * LED lifespan: at least 50,000 hrs. * Maximum center illumination level, at 1m distance: 160,000 lux. Without shadows. * Head/Dome diameter: 700 mm ± 10%. * Color temperature adjustment range: From 4,000 to 5,000 K or wider range. * Color rendering index: at least 95. * Controls   + On/Off switch.   + Light intensity.   + Color temperature. * Chassis and external components must be built of materials, and/or have a finish/coating resistant to corrosion and the application of disinfectants commonly used in healthcare premises.   **Movements:**   * Head/Dome, at least:   + Horizontal/Longitudinal axle: ± 180°   + Horizontal/Transversal axle: ± 180° * Arm, at least:   + Transversal axle: At least 75°   **Accessories:**   * One (1) power supply cable. * Two hundred (200) disposable sterile handle covers. * Two (2) removable and autoclavable handles, sterilized with saturated steam under pressure @ 134 °C or higher temperature.   *NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product during the first 12 months, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included and listed in the offer.* | 4 |
| **Documentation required:**  Bidder shall furnish the following documents:   * Manufacturer brochure or data sheet including at least all technical specifications required. * User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal. * Service manuals must be provided including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits. * List of all common spare parts and accessories with part numbers. * Manufacturer authorization Letter. * Commitment manufacturer letter including:   + installation and commissioning on site would be performed by the manufacturer or his representative in the country (according to the general requirements in the bid document under the clause “Installation and commissioning on site").   + at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause “Warranty").   + at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause “Post-sale Services").   + training on use, cleaning, and disinfecting for the healthcare staff, and basic maintenance for the technical staff, in Ukrainian and English language (according to the general requirements in the bid document under the clause “Training").   **NOTE: All the documents must be submitted in English and Ukrainian language as mandatory. The Russian language could be accepted as an exception to the Ukrainian language.** |  |
| **Regulatory approvals required:**  Bidder shall furnish **documentary evidence** to demonstrate that the good offered is approved according:   * Valid certificate or approval letter from national Ukrainian regulatory body, which confirms local registration of the product and permission to use it in medical practice. * Valid manufacturing licenses. * And at least one of the following regulatory approvals and certificates:   + Declaration of Conformity (DoC) according with regulation 2017/745 for Medical Devices Class I or,   + FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or   Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan. |  |
| **Safety & product Standards:**  Bidder shall furnish the following documents:   * Valid ISO 13485 certificate. * Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety & regulatory standards:   + IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance   + IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests   + IEC 60601-2-41: Medical Electrical Equipment, Part 2-41: Particular Requirements for the Safety of Surgical Luminaires and Luminaires for Diagnosis. |  |
| 1. **Ceiling surgical lamp double-dome** | **Quantity, pcs:** |
| **Product Description**  Surgical lamp designed to provide a specialized source of light during a surgical intervention.  **Electrical Requirements:**   * Power requirements according to Ukraine standards: 220 VAC ± 10%, 50 Hz. * Electrical wiring system, grounded.   **Technical specifications:**   * Ceiling system, one anchoring point. * Double dome with independent and articulating arms. * LED technology. * LED lifespan: at least 50,000 hrs. * First dome (D1)   + Diameter: ≥ 50 cm.   + Multiple LEDs ≥ 50 Units. * Second dome (D2)   + Diameter: ≥ 70 cm.   + Multiple LEDs ≥ 70 Units. * Maximum center illumination level, at 1m distance: 120,000 lux. Without shadows. * Color temperature: between 4,000 and 5,000 K. * Color rendering index: at least 90. * Control with On/Off control and light intensity. * Intensity adjustment: at least 3 levels. * Diameter of the light field: At least from 15 to 30 cm or wider range, adjustable by means of handle rotation. * Housing material: metal. * Chassis and external components must be built of materials, and/or have a finish/coating resistant to corrosion and the application of disinfectants commonly used in healthcare premises.   **Movements:**   * Dome, at least:   + Vertical movement of each dome-arm ≥ ±45°.   + Lateral movement of each dome ≥ ±30°. * Arms, rotational degrees of freedom: 360°.   **Accessories:**   * One hundred (100) disposable sterile handle covers. * Four (4) removable and autoclavable handles, sterilized with saturated steam under pressure @ 134 °C or higher temperature.   *NOTE: All other necessary accessories, consumables and spare for the correct installation and operation of the product, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included and listed in the offer.* | 2 |
| **Documentation required:**  Bidder shall furnish the following documents:   * Manufacturer brochure or data sheet including at least all technical specifications required. * User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal. * Service manuals must be provided including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits. * List of all common spare parts and accessories with part numbers. * Manufacturer authorization Letter. * Commitment manufacturer letter including:   + safety and operational checks prior to delivery, installation and commissioning on site would be performed by the manufacturer or his representative in the country (according to the general requirements in the bid document under the clause “Installation and commissioning on site").   + at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause “Warranty").   + at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause “Post-sale Services").   + training on use, cleaning, and disinfecting for the healthcare staff, and basic maintenance for the technical staff, in Ukrainian and English language (according to the general requirements in the bid document under the clause “Training").   **NOTE: All the documents must be submitted in English and Ukrainian language as mandatory. The Russian language could be accepted as an exception to the Ukrainian language.** |  |
| **Regulatory approvals required:**  Bidder shall furnish **documentary evidence** to demonstrate that the good offered is approved according:   * Valid certificate or approval letter from national Ukrainian regulatory body, which confirms local registration of the product and permission to use it in medical practice. * Valid manufacturing licenses. * And at least one of the following regulatory approvals and certificates:   + Declaration of Conformity (DoC) according with regulation 2017/745 for Medical Devices Class I or,   + FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or   Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan. |  |
| **Safety & product Standards:**  Bidder shall furnish the following documents:   * Valid ISO 13485 certificate. * Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety & regulatory standards:   + IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance   + IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests   + IEC 60601-2-41: Medical Electrical Equipment, Part 2-41: Particular Requirements for the Safety of Surgical Luminaires and Luminaires for Diagnosis. |  |

|  |  |
| --- | --- |
| 1. **Mobile bactericidal irradiator** | **Quantity, pcs:** |
| **Product Description**  Mobile device designed for disinfection of hospital and other premises air and surfaces in the presence and absence of people, employing UV-C light.  **Electrical Requirements:**   * Power requirements according to Ukraine standards: 220 VAC ± 10%, 50 Hz. * Power cord with “F” type plug for medical devices.   **Technical specifications:**   * Light features:   + Peak UV-C light wavelength: 254nm   + UV-C radiation power after 100 hours: 105 Watts   + Lamp lifespan: at least 15,000 hrs. * Performance:   + Effective room area: At least up to 1000m2.   + Electronic star system.   + Number of active lamps: At least six.   + Ozone-free lamps.   + With uviol glass, highly permeable to UV-C light. * Mobile irradiator, mounted on a base stand. * Base with at least four (4) anti-static swivel castors. A minimum of two (2) castors with brakes. * Housing material: metal. * Chassis and external components must be built of materials, and/or have a finish/coating resistant to corrosion and the application of disinfectants commonly used in healthcare premises.   **Accessories:**   * One (1) power supply cable.   *NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product during the first 12 months, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included and listed in the offer.* | 7 |
| **Documentation required:**  Bidder shall furnish the following documents:   * Manufacturer brochure or data sheet including at least all technical specifications required. * User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal. * Service manuals must be provided including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits. * List of all common spare parts and accessories with part numbers. * Manufacturer authorization Letter. * Commitment manufacturer letter including:   + installation and commissioning on site would be performed by the manufacturer or his representative in the country (according to the general requirements in the bid document under the clause “Installation and commissioning on site").   + at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause “Warranty").   + at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause “Post-sale Services").   + training on use, cleaning, and disinfecting for the healthcare staff, and basic maintenance for the technical staff, in Ukrainian and English language (according to the general requirements in the bid document under the clause “Training").   **NOTE: All the documents must be submitted in English and Ukrainian language as mandatory. The Russian language could be accepted as an exception to the Ukrainian language.** |  |
| **Regulatory approvals required:**  Bidder shall furnish **documentary evidence** to demonstrate that the good offered is approved according:   * Valid certificate or approval letter from national Ukrainian regulatory body, which confirms local registration of the product and permission to use it in medical practice. * Valid manufacturing licenses. * And at least one of the following regulatory approvals and certificates:   + Declaration of Conformity (DoC) according with regulation 2017/745 for Medical Devices Class I or,   + FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or   Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan. |  |
| **Safety & product Standards:**  Bidder shall furnish the following documents:   * Valid ISO 13485 certificate. * Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety & regulatory standards:   + IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance   + IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests |  |
| 1. **Instruments Drying cabinet** | **Quantity, pcs:** |
| **Product Description**  Used in Drying, Baking, Disinfecting, Sterilization, Laboratory, Research, Engineering, Industry, Thermostat storage, Heating Storage. Also known as Heating Oven, Laboratory Drying Oven.  **Electrical Requirements:**   * Power requirements according to Ukraine standards: 220 VAC ± 10%, 50 Hz. * Power cord with “F” type plug for medical devices. * Power consumption (max): 3.5 kW   **Technical specifications:**   * Inner chamber made of Stainless steel AISI 304 and fiberglass insulation between the inner and outer walls to maximize thermal efficiency. * Ceramic fiber or similar door seal, for high temperature resistance. * *Optional:* The equipment can be provided with a glass observation window that allows examination without need of opening the door. * Forced air convection system which maintains temperature uniformity. * Easy cleaning of interior with mirror polish walls, and rounded corners. The exterior should be easy to clean; temperature resistant epoxi-type coating is expected. * 2- 4 (four) shelves with a minimum of 80mm height between them. * Programmable PID controller with programmable steps and period, boot and shutdown time can be preset, * Adjustable circulating fan independent over-temperature alarm system ensures experiments running safely. * Control panel with electronic display showing current temperature, setting target temperature and programmed/remaining time. Visual indicator of the process stage. Pre-configured operating modes must be provided according to the standard practice. * Heating Time setting: 30 ± 5 minutes to 150 ± 5 minutes. * Display Resolution 0.1°C * Timer Range 0-5999 min * Alarms: Over temperature, Time ending, Lack of Energy, Emergency stop. * Maximum Temperature Deviation: ± 3°C * Chamber volume: 150 to 180 L. Approximate dimensions: Width 500mm x Height 700mm x Depth 500mm without stand table.   **Accessories:**   * Cabinet stand must be built of materials, and/or have a finish/coating resistant to corrosion and the application of disinfectants commonly used in healthcare premises.   *NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product during the first 12 months, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included and listed in the offer.* | 2 |
| **Documentation required:**  Bidder shall furnish the following documents:   * Manufacturer brochure or data sheet including at least all technical specifications required. * User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal. * Service manuals must be provided including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits. * List of all common spare parts and accessories with part numbers. * Manufacturer authorization Letter. * Commitment manufacturer letter including:   + installation and commissioning on site would be performed by the manufacturer or his representative in the country (according to the general requirements in the bid document under the clause “Installation and commissioning on site").   + at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause “Warranty").   + at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause “Post-sale Services").   + training on use, cleaning, and disinfecting for the healthcare staff, and basic maintenance for the technical staff, in Ukrainian and English language (according to the general requirements in the bid document under the clause “Training").   **NOTE: All the documents must be submitted in English and Ukrainian language as mandatory. The Russian language could be accepted as an exception to the Ukrainian language.** |  |
| **Regulatory approvals required:**  Bidder shall furnish **documentary evidence** to demonstrate that the good offered is approved according:   * Valid certificate or approval letter from national Ukrainian regulatory body, which confirms local registration of the product and permission to use it in medical practice. * Valid manufacturing licenses. * And at least one of the following regulatory approvals and certificates:   + European Certificate of Conformity (CE) (or equivalent) with Regulation 2017/745 or Directive 93/42 EC and Agreement Letter signed with the NB demonstrating the on-going MDR application.   + FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States.   Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan. |  |
| **Safety & product Standards:**  Bidder shall furnish the following documents:   * Valid ISO 13485 certificate. * Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety & regulatory standards:   + IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance   IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests |  |
| 1. **Ultrasonic washer** | **Quantity, pcs:** |
| **Product Description**  This tabletop apparatus is equipped with a stainless-steel container chamber and ultrasonic piezoelectric emitters mounted on the base, emitting mechanical waves within the ultrasound frequency spectrum. When energized by alternating current, these emitters transmit energy through the water within the chamber to the target material.  The functionality of this cleaning device hinges on the principle of cavitation, whereby countless minuscule air bubbles rapidly form and collapse within the liquid medium, facilitating the mechanical extraction of particles.  **Electrical Requirements:**   * Power requirements according to Ukraine standards: 220 VAC ± 10%, 50 Hz. * Power cord with “F” type plug for medical devices. * Power consumption (max): 800 W   **Technical specifications:**   * Cleaning chamber and Cover Lid made of AISI 304 Stainless Steel. * Useful Capacity: 30 L * Ultrasound power: 600 W * Ultrasound Frequency: 40KHz * Heating regulation 20 - 80°C. * Heating ON/OFF switch by user. * Heating power: 500 W * Digital Timer: 1 - 30 minutes (1-minute steps) * Drainage of water through a faucet or valve. * Internal dimensions (tank): 50x30x20 cm * External dimensions: 53x32.5x32.5 cm * Weight: 10 - 15 kg * Digital display that shows real time Heating Temperature and Timer * Control panel with Heating Temperature and Timer adjustment with soft touch or dial controls. * Visual indicators of operation when heating and/or ultrasound are operating. * Side handles for easy transport to the site of use and maintenance. * ON/OFF main switch with 3A fuse   **Accessories:**   * 1 x Stainless steel grid or basket for small pieces positioning * 1 x Spare fuse (3A) * Ultrasonic washer stand must be built of materials, and/or have a finish/coating resistant to corrosion and the application of disinfectants commonly used in healthcare premises.   *NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product during the first 12 months, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included and listed in the offer.* | 2 |
| **Documentation required:**  Bidder shall furnish the following documents:   * Manufacturer brochure or data sheet including at least all technical specifications required. * User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal. * Service manuals must be provided including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits. * List of all common spare parts and accessories with part numbers. * Manufacturer authorization Letter. * Commitment manufacturer letter including:   + installation and commissioning on site would be performed by the manufacturer or his representative in the country (according to the general requirements in the bid document under the clause “Installation and commissioning on site").   + at least one (1) year of full onsite warranty (according to the general requirements in the bid document under the clause “Warranty").   + at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause “Post-sale Services").   + training on use, cleaning, and disinfecting for the healthcare staff, and basic maintenance for the technical staff, in Ukrainian and English language (according to the general requirements in the bid document under the clause “Training").   **NOTE: All the documents must be submitted in English and Ukrainian language as mandatory. The Russian language could be accepted as an exception to the Ukrainian language.** |  |
| **Regulatory approvals required:**  Bidder shall furnish **documentary evidence** to demonstrate that the good offered is approved according:   * Valid certificate or approval letter from national Ukrainian regulatory body, which confirms local registration of the product and permission to use it in medical practice. * Valid manufacturing licenses. * And at least one of the following regulatory approvals and certificates:   + Declaration of Conformity (DoC) according to Machinery Directive 2006/42/EU and/or Electromagnetic Compatibility Directive 2014/30/EU or,   + US FDA (Food and Drug Administration) pre-market authorization for the United States. For class I devices the listing evidence is enough or,   When applicable, other regulatory international bodies for example IMDRF founding member countries such as Australia, Canada, or Japan. |  |
| **Safety & product Standards:**  Bidder shall furnish the following documents:   * Valid ISO 9001 certificate, preferably ISO 13485 certificate. * Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow standards:   + EN 60335-1 / IEC 60335-1: Household and similar electrical appliances - Safety - Part 1: General requirements   + EN 62233 / IEC 62233 Measurement methods for electromagnetic fields of household appliances and similar apparatus with regard to human exposure   + EN IEC 61000-6-2 / IEC 61000-6-2: Electromagnetic compatibility (EMC) - Part 6-2: Generic standards - Immunity standard for industrial environments   + EN IEC 61000-6-3 / IEC 61000-6-3: Electromagnetic compatibility (EMC) - Part 6-3: Generic standards - Emission standard for equipment in residential environments |  |
| 1. **Automated external defibrillator (AED)** | **Quantity, pcs:** |
| **Product Description**  Automated External Defibrillator (AED) for adult and pediatric patients, compact and portable, battery powered, with accessories. Designed to treat Ventricular Fibrillation (VF) and Fast Ventricular Tachycardia (VT).  **Electrical Requirements:**   * Replaceable internal battery operation   **Technical specifications:**   * For adult and child patients * Pictograms and voice prompts to guide the user through AED and CPR. * Automatic ECG analysis and Ventricular Fibrillation (VF) and Fast Ventricular Tachycardia (VT) detection. * Automatic switch between AED and CPR modes based on analysis. * Operating mode: semi-automatic * Waveform: biphasic exponential; impedance compensated * Automatic power charging. Charging time: <7 seconds, with new battery * Energy: adult: 200 J - child: 50 J using attenuated pediatric pads or configuration from the device * Pediatric dose attenuation through pediatric pads with energy attenuation available, or built-in power reduction switch for pediatric patients. * Controls: at least shock button and On/Off button * Pacemaker detection * Built-in discharge feature * Data stored: at least 60 minutes of ECG and events. * Automatic self-test * Alarms for operational status * Battery capacity: at least 140 shocks, or 2 hours of continuous monitoring * Standby duration: at least 4 years * Indications and messages on the equipment must be in English language as mandatory, and preferably also in Ukrainian language.   **Accessories:**   * Three (3) Self-adhesive defibrillation/monitoring pads for pediatrics. With energy attenuation if a built-in power reduction switch is not available for pediatric patients. Shelf life of pads at least 2 years * Three (3) Self-adhesive defibrillation/monitoring pads for adults. Shelf life of pads at least 2 years * Disposable battery * Carrying bag   *NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product during the first 12 months, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included and listed in the offer.* | 3 |
| **Documentation required:**  Bidder shall furnish the following documents:   * Manufacturer brochure or data sheet including at least all technical specifications required. * User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal. * Service manuals must be provided including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits. * List of all common spare parts and accessories with part numbers. * Manufacturer authorization Letter. * Commitment manufacturer letter including:   + installation and commissioning on site would be performed by the manufacturer or his representative in the country (according to the general requirements in the bid document under the clause “Installation and commissioning on site").   + at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause “Warranty").   + at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause “Post-sale Services").   + training on use, cleaning, and disinfecting for the healthcare staff, and basic maintenance for the technical staff, in Ukrainian and English language (according to the general requirements in the bid document under the clause “Training").   **NOTE: All the documents must be submitted in English and Ukrainian language as mandatory. The Russian language could be accepted as an exception to the Ukrainian language.** |  |
| **Regulatory approvals required:**  Bidder shall furnish **documentary evidence** to demonstrate that the good offered is approved according:   * Valid certificate or approval letter from national Ukrainian regulatory body, which confirms local registration of the product and permission to use it in medical practice. * Valid manufacturing licenses. * And at least one of the following regulatory approvals and certificates:   + European Certificate of Conformity (CE) with Regulation 2017/745 or Directive 93/42 EC and Agreement Letter signed with the NB demonstrating the on-going MDR application, for Class III devices, or   + FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or   Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan. |  |
| **Safety & product Standards:**  Bidder shall furnish the following documents:   * Valid ISO 13485 certificate. * Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety & regulatory standards:   + IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance   + IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests   + IEC 60601-2-4: Medical electrical equipment - Part 2-4: Particular requirements for the safety of cardiac defibrillators. |  |
| 1. **Digital newborn scale** | **Quantity, pcs:** |
| **Product Description**  Electronic table scale designed to measure the weight of a newborn, or to monitor weight changes.  **Electrical Requirements:**   * Power requirements: replaceable lithium batteries operated.   **Technical specifications:**   * Electronic table scale for newborns * Weighing range at least 0 - 10 kg * Minimum graduation: at least 5 g. * Accuracy: ±5g. * Digital display * Measuring unit: Kg * Automatic switch-off * Tara function * Hold function. * Zero setting * Auto-calibration with each switch-on. * Tray for infant curved for patient containment. * All surfaces antioxidant, resistant to corrosion of hospital grade disinfectants.   **Accessories:**   * Two (2) replaceable lithium batteries.   *NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product during the first 12 months, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included and listed in the offer.* | 3 |
| **Documentation required:**  Bidder shall furnish the following documents:   * Manufacturer brochure or data sheet including at least all technical specifications required. * User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal. * Service manuals must be provided including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits. * List of all common spare parts and accessories with part numbers. * Manufacturer authorization Letter. * Factory calibration certificate is required. * Commitment manufacturer letter including:   + at least one (1) year of full onsite warranty (according to the general requirements in the bid document under the clause “Warranty").   + at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause “Post-sale Services").   + training on use, cleaning, and disinfecting for the healthcare staff, and basic maintenance for the technical staff, in Ukrainian and English language (according to the general requirements in the bid document under the clause “Training").   **NOTE: All the documents must be submitted in English and Ukrainian language as mandatory. The Russian language could be accepted as an exception to the Ukrainian language.** |  |
| **Regulatory approvals required:**  Bidder shall furnish **documentary evidence** to demonstrate that the good offered is approved according:   * Valid certificate or approval letter from national Ukrainian regulatory body, which confirms local registration of the product and permission to use it in medical practice. * Valid manufacturing licenses. * And at least one of the following regulatory approvals and certificates:   + Declaration of Conformity (DoC) according with regulation 2017/745 for Medical Devices Class Im.   + FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or   Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan. |  |
| **Safety & product Standards:**  Bidder shall furnish the following documents:   * Valid ISO 13485 certificate. * Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety & regulatory standards:   + IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance   IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests. |  |

|  |  |
| --- | --- |
| 1. **Oxygen concentrator (20 L/min)** | **Quantity, pcs:** |
| **Product Description**  Device designed to concentrate oxygen from indoor/outdoor ambient air and deliver it at high pressure to devices for mechanical pulmonary respiration, anesthesia, and oxygen therapy.  **Electrical Requirements:**   * Power requirements according to Ukraine standards: 220 VAC ± 10%, 50 Hz. * Power cord with “F” type plug for medical devices.   **Technical specifications:**   * Pressure Swing Adsorption technology. * Free-oil compressor. * Dehumidifier: refrigerated air dryer type. * System mounted on stable, mobile trolley fitted with 4 caster antistatic wheels with brake system. * Provides continuous flow of concentrated oxygen at least 93% ± 3%, from indoor/outdoor ambient air @ 21% oxygen. * Oxygen sensing device is integrated and measures concentration at the flow meter entrance. * Delivered and controlled flow: From 1 to 20 LPM or wider range. * Delivered and controlled outlet pressure: From 20 to 60 PSI or wider range. * With a flow meter for measuring and controlling delivered flow, full scale up to 20 LPM and with markings at 0.5 L intervals. * Delivered oxygen pressure gauge and regulator, full scale up to 60 PSI. * Control panel:   + On/Off switch.   + Power On indicator.   + Acceptable oxygen concentration indicator.   + Flow meter: Tube type with ball o ball or bobbin indicator.   + Manometer: Full scale round manometer.   + LCD, TFT, LED Display showing at least:     - * Oxygen output pressure.       * Compressor temperature.       * Operating time.       * Accumulative operating time.   + Continuous monitoring, with visual and audible alarm at least for:     - * Low/ high output pressure       * Low oxygen concentration < 83%       * High temperature * Oxygen outlet durable, with approx. 6mm barbed fitting or equivalent. * Sound level produced: less than 60 dB @ 1m. * Chassis and external components must be built of materials, and/or have a finish/coating resistant to corrosion and the application of disinfectants commonly used in healthcare premises.   **Accessories:**   * One (1) power supply cable. * Tubing adapter kit, quantity as necessary. * Four (4) x Set of spare filters (coarse, pre-filter, inlet filter, bacterial filter or as necessary according to the offered devices).   *NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product during the first 12 months, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included and listed in the offer.* | 2 |
| **Documentation required:**  Bidder shall furnish the following documents:   * Manufacturer brochure or data sheet including at least all technical specifications required. * User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal. * Service manuals must be provided including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits. * List of all common spare parts and accessories with part numbers. * Manufacturer authorization Letter. * Commitment manufacturer letter including:   + installation and commissioning on site would be performed by the manufacturer or his representative in the country (according to the general requirements in the bid document under the clause “Installation and commissioning on site").   + at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause “Warranty").   + at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause “Post-sale Services").   + training on use, cleaning, and disinfecting for the healthcare staff, and basic maintenance for the technical staff, in Ukrainian and English language (according to the general requirements in the bid document under the clause “Training").   **NOTE: All the documents must be submitted in English and Ukrainian language as mandatory. The Russian language could be accepted as an exception to the Ukrainian language.** |  |
| **Regulatory approvals required:**  Bidder shall furnish **documentary evidence** to demonstrate that the good offered is approved according:   * Valid certificate or approval letter from national Ukrainian regulatory body, which confirms local registration of the product and permission to use it in medical practice. * Valid manufacturing licenses. * And at least one of the following regulatory approvals and certificates:   + European Certificate of Conformity (CE) with Regulation 2017/745 or Directive 93/42 EC and Agreement Letter signed with the NB demonstrating the on-going MDR application, for Class IIb devices, or   + FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or   Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan. |  |
| **Safety & product Standards:**  Bidder shall furnish the following documents:   * Valid ISO 13485 certificate. * Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety & regulatory standards:   + IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance   + IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests   ISO 80601-2-69: Medical electrical equipment - Part 2-69: Particular requirements for the basic safety and essential performance of oxygen concentrator equipment. |  |
| 1. **Oxygen concentrator (10 L/min)** | **Quantity, pcs:** |
| **Product Description**  Device designed to concentrate oxygen from indoor/outdoor ambient air and deliver it at low pressure directly to the patient for oxygen therapy.  **Electrical Requirements:**   * Power requirements according to Ukraine standards: 220 VAC ± 10%, 50 Hz. * Power cord with “F” type plug for medical devices.   **Technical specifications:**   * Free-oil compressor. * System mounted on stable, mobile trolley fitted with 4 caster antistatic wheels with brake system. * Integrated handle allows for easy moving and positioning. * Provides continuous flow of concentrated oxygen at least 93% ± 3%, from indoor/outdoor ambient air @ 21% oxygen. * Oxygen sensing device is integrated and measures concentration at the flow meter entrance. * Delivered and controlled flow: From 1 to 10 LPM or wider range. * Delivered and controlled outlet pressure: From 6 to 8 PSI or wider range. * With a flow meter for measuring and controlling delivered flow, full scale up to 10 LPM and with markings at 0.5 L intervals. * Control panel:   + On/Off switch.   + Power On indicator.   + Flow meter: Tube type with ball o ball or bobbin indicator.   + LCD, TFT, LED Display,   + Continuous monitoring, with visual and audible alarm for pressure failure. * Oxygen outlet durable, with approx. 6mm barbed fitting or equivalent. * Sound level produced: less than 60 dB @ 1m. * Chassis and external components must be built of materials, and/or have a finish/coating resistant to corrosion and the application of disinfectants commonly used in healthcare premises.   **Accessories:**   * One (1) power supply cable. * Tubing adapter kit, quantity as necessary. * Four (4) x Set of spare filters (coarse, pre-filter, inlet filter, bacterial filter or as necessary according to the offered devices).   *NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product during the first 12 months, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included and listed in the offer.* | 2 |
| **Documentation required:**  Bidder shall furnish the following documents:   * Manufacturer brochure or data sheet including at least all technical specifications required. * User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal. * Service manuals must be provided including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits. * List of all common spare parts and accessories with part numbers. * Manufacturer authorization Letter. * Commitment manufacturer letter including:   + installation and commissioning on site would be performed by the manufacturer or his representative in the country (according to the general requirements in the bid document under the clause “Installation and commissioning on site").   + at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause “Warranty").   + at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause “Post-sale Services").   + training on use, cleaning, and disinfecting for the healthcare staff, and basic maintenance for the technical staff, in Ukrainian and English language (according to the general requirements in the bid document under the clause “Training").   **NOTE: All the documents must be submitted in English and Ukrainian language as mandatory. The Russian language could be accepted as an exception to the Ukrainian language.** |  |
| **Regulatory approvals required:**  Bidder shall furnish **documentary evidence** to demonstrate that the good offered is approved according:   * Valid certificate or approval letter from national Ukrainian regulatory body, which confirms local registration of the product and permission to use it in medical practice. * Valid manufacturing licenses. * And at least one of the following regulatory approvals and certificates:   + European Certificate of Conformity (CE) with Regulation 2017/745 or Directive 93/42 EC and Agreement Letter signed with the NB demonstrating the on-going MDR application, for Class IIb devices, or   + FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or   Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan. |  |
| **Safety & product Standards:**  Bidder shall furnish the following documents:   * Valid ISO 13485 certificate. * Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety & regulatory standards:   + IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance   + IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests   + ISO 80601-2-69: Medical electrical equipment - Part 2-69: Particular requirements for the basic safety and essential performance of oxygen concentrator equipment. |  |
| 1. **Blood plasma freezer** | **Quantity, pcs:** |
| **Product Description**  The plasma freezer is designed to store fresh frozen plasma at low temperatures.    **Electrical Requirements:**   * Power requirements according to Ukraine standards: 220 VAC ± 10%, 50 Hz. * Power cord with “F” type plug for medical devices.   **Technical specifications:**   * Volume: at least 195 Liters * Range of temperature: -25ºC to -45ºC. * Single compressor * Type of refrigerant: R290 * Static internal air distribution * Materials: painted steel, corrosion resistant. * Cyclopentane Insulation. * Single door with key lock. * Alarms: at least for high/ low temperatures and temperature probe failure. * Energy saving system without compromising quality. * Castor wheels for ease of mobility.   **Accessories:**   * Basket: at least 1 basket for plasma.   *NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product during the first 12 months, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included and listed in the offer.* | 1 |
| **Documentation required:**  Bidder shall furnish the following documents:   * Manufacturer brochure or data sheet including at least all technical specifications required. * User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal. * Service manuals must be provided including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits. * List of all common spare parts and accessories with part numbers. * Manufacturer authorization Letter. * Commitment manufacturer letter including:   + installation and commissioning on site would be performed by the manufacturer or his representative in the country (according to the general requirements in the bid document under the clause “Installation and commissioning on site").   + at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause “Warranty").   + at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause “Post-sale Services").   + training on use, cleaning, and disinfecting for the healthcare staff, and basic maintenance for the technical staff, in Ukrainian and English language (according to the general requirements in the bid document under the clause “Training").   **NOTE: All the documents must be submitted in English and Ukrainian language as mandatory. The Russian language could be accepted as an exception to the Ukrainian language.** |  |
| **Regulatory approvals required:**  Bidder shall furnish **documentary evidence** to demonstrate that the good offered is approved according:   * Valid certificate or approval letter from national Ukrainian regulatory body, which confirms local registration of the product and permission to use it in medical practice. * Valid manufacturing licenses. * And at least one of the following regulatory approvals and certificates:   + Declaration of Conformity (DoC) according to Machinery Directive 2006/42/EU and/or Electromagnetic Compatibility Directive 2014/30/EU or,   + US FDA (Food and Drug Administration) pre-market authorization for the United States. For class I devices the listing evidence is enough or,   When applicable, other regulatory international bodies for example IMDRF founding member countries such as Australia, Canada, or Japan. |  |
| **Safety & product Standards:**  Bidder shall furnish the following documents:   * Valid ISO 9001 certificate, preferably ISO 13485 certificate. * Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow standards:   + EN 60335-1 / IEC 60335-1: Household and similar electrical appliances - Safety - Part 1: General requirements   + EN 62233 / IEC 62233 Measurement methods for electromagnetic fields of household appliances and similar apparatus with regard to human exposure   + EN IEC 61000-6-2 / IEC 61000-6-2: Electromagnetic compatibility (EMC) - Part 6-2: Generic standards - Immunity standard for industrial environments   + EN IEC 61000-6-3 / IEC 61000-6-3: Electromagnetic compatibility (EMC) - Part 6-3: Generic standards - Emission standard for equipment in residential environments   + DIN 13277 Refrigerators and freezers for laboratory and medical applications - Terminology, requirements, testing. |  |
| 1. **Pharmacy refrigerator** | **Quantity, pcs:** |
| **Product Description**  Refrigerator designed for the storage and preservation of pharmaceutical products, at specific temperature range to protect, control and maintain their quality and safety.  **Electrical Requirements:**   * Power requirements according to Ukraine standards: 220 VAC ± 10%, 50 Hz. * Power cord with “F” type plug.   **Technical specifications:**   * Microprocessed and/or microcontrolled. * Control Panel:   + Automatic temperature control   + Digital display allows the visualization of the programmed temperature and the effective temperature.   + With built-in temperature recorder and system for downloading data.   + Membrane keyboard or touch screen, with menu and options in English and/or Ukrainian. With user and equipment interaction complemented with pictorial resources.   + Temperature range management between +2 and +15 °C, preset at +5°C.   + Visible and audible alarm for temperature out of range and power failure.   + With internal battery backup for monitoring and alarm system.   + With a safety thermostat. * Interior design:   + Minimum capacity of 510 liters (18 cubic feet).   + Air forced cooling and automatic defrosting system.   + With 4 internal, open and removable shelves for storing the products.   + Access for external probe.   + Interior in stainless steel AISI 304.   + LED light-activated when opening the door. * Exterior design:   + One single door, with double tempered glass.   + Door with handle.   + Stainless steel, steel with a baked electrostatic paint finish, or similar high-quality material that ensures durability, safety, stability, resistance to corrosion.   + With four wheels and brake system. * Cooling and thermal insulation system free of CFC, HCFC. * Gas refrigerant for cooling: R290 or R600a. * Chassis and external components must be built of materials, and/or have a finish/coating resistant to corrosion and the application of disinfectants for hospital use.   **Accessories:**   * One (1) power supply cable. * One (1) USB memory stick   *NOTE: All the necessary accessories for the correct operation of the product, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included.* | 2 |
| **Documentation required:**  Bidder shall furnish the following documents:   * Manufacturer brochure or data sheet including at least all technical specifications required. * User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal. * Service manuals must be provided including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits. * List of all common spare parts and accessories with part numbers. * Manufacturer authorization Letter. * Commitment manufacturer letter including:   + installation and commissioning on site would be performed by the manufacturer or his representative in the country (according to the general requirements in the bid document under the clause “Installation and commissioning on site").   + at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause “Warranty").   + at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause “Post-sale Services").   + training on use, cleaning, and disinfecting for the healthcare staff, and basic maintenance for the technical staff, in Ukrainian and English language (according to the general requirements in the bid document under the clause “Training").   **NOTE: All the documents must be submitted in English and Ukrainian language as mandatory. The Russian language could be accepted as an exception to the Ukrainian language.** |  |
| **Regulatory approvals required:**  Bidder shall furnish **documentary evidence** to demonstrate that the good offered is approved according:   * Valid certificate or approval letter from national Ukrainian regulatory body, which confirms local registration of the product and permission to use it in medical practice. * Valid manufacturing licenses. * And at least one of the following regulatory approvals and certificates:   + Declaration of Conformity (DoC) according to Machinery Directive 2006/42/EU and/or Electromagnetic Compatibility Directive 2014/30/EU or,   + US FDA (Food and Drug Administration) pre-market authorization for the United States. For class I devices the listing evidence is enough or,   When applicable, other regulatory international bodies for example IMDRF founding member countries such as Australia, Canada, or Japan. |  |
| **Safety & product Standards:**  Bidder shall furnish the following documents:   * Valid ISO 9001 certificate, preferably ISO 13485 certificate. * Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow standards:   + EN 60335-2-89: Household and similar electrical appliances - Safety - Part 2-89: Particular requirements for commercial refrigerating appliances with an incorporated or remote refrigerant unit or compressor.   + DIN 13277 Refrigerators and freezers for laboratory and medical applications - Terminology, requirements, testing |  |
| 1. **Transcutaneous bilirubinometer** | **Quantity, pcs:** |
| **Product Description**  Transcutaneous bilirubinometer (TcB) is a noninvasive point-of-care intended for quantification of serum bilirubin in neonates for the diagnosis and management of jaundice. TcB measures cutaneous bilirubin by directing light into the skin and measuring the intensity of reflecting specific wavelengths. The device measures the transcutaneous bilirubin levels in mg/dL or μmol/L when the device probe is pressed on the newborn forehead or sternum.  **Electrical Requirements:**   * Power charger requirements according to Ukraine standards: Voltage input: 220 VAC ± 10%, 50 Hz. * Power cord with “F” type plug for medical devices. * Rechargeable internal Lithium batteries with a charging station plugged through a power charger. * Internally powered ME equipment, Type BF, continuous operation (under IEC 60601-1)   **Technical specifications:**   * Light source type: xenon flash lamp * Light source lifetime: Approx 150000 measures * Color Display 3'' with touch screen * Measurement Range: Linear 0.0 to 25.0mg/dL or 0 to 425 μmol/L * Accuracy: +/-10% (without previous phototherapy) * Repeatability: <3% * Data storage of at least 100 patient measures * Approximate size Height: 150mm, Width: 50mm and Depth: 350 mm (mounted on the charging station). Intended to be used on the desktop when charging and portable during use. * Data transmission USB port or Bluetooth. * Autocalibration with minimum intervention of the user.   **Accessories:**   * Carrying case for storage and transport * Optical probes for automatic calibration (if not included in the main unit)   *NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product during the first 12 months, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included and listed in the offer.* | 3 |
| **Documentation required:**  Bidder shall furnish the following documents:   * Manufacturer brochure or data sheet including at least all technical specifications required. * User manual must be provided including operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal. * Service manuals must be provided including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits. * Factory calibration certificate is required. * List of all common spare parts and accessories with part numbers. * Manufacturer authorization Letter. * Commitment manufacturer letter including:   + at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause “Warranty").   + at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause “Post-sale Services").   + training on use, cleaning, and disinfecting for the healthcare staff, and basic maintenance for the technical staff, in Ukrainian and English language (according to the general requirements in the bid document under the clause “Training").   **NOTE: All the documents must be submitted in English and Ukrainian language as mandatory. The Russian language could be accepted as an exception to the Ukrainian language.** |  |
| **Regulatory approvals required:**  Bidder shall furnish **documentary evidence** to demonstrate that the good offered is approved according:   * Valid certificate or approval letter from national Ukrainian regulatory body, which confirms local registration of the product and permission to use it in medical practice. * Valid manufacturing licenses. * And at least one of the following regulatory approvals and certificates:   + EU classification: Class IIa. European Certificate of Conformity (CE) with Regulation 2017/745 or Directive 93/42 EC and Agreement Letter signed with the NB demonstrating the on-going MDR application for this class of products.   + FDA (Food and Drug Administration) of the USA that certifies pre-market authorization in the United States (510k certificate in case of Class IIa).   + Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan. |  |
| **Safety & product Standards:**  Bidder shall furnish the following documents:   * Valid ISO 13485 certificate. * Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety & regulatory standards:   + IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance   IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests |  |
| 1. **Syringe pump** | **Quantity, pcs:** |
| **Product Description**  Devices designed to accurately deliver liquids through intravenous (IV) or epidural routes for therapeutic and/or diagnostic purposes.  The syringe pump is designed to precisely drive the plunger of a syringe down its barrel to infuse a solution when it must be administered with a high degree of volume accuracy and rate consistency. Because of the lower flow settings and flow resolution, it is especially appropriate for neonatal, infant, and critical care applications in which small volumes of concentrated drugs are to be delivered over an extended period. It can also be used to administer epidural analgesia.  **Electrical Requirements:**   * Power requirements according to Ukraine standards: 220 VAC ± 10%, 50 Hz. * Power cord with “F” type plug for medical devices. * Built-in rechargeable battery, allowing at least 3 hours of continuous operation.   **Technical specifications:**   * Robust design allows use in demanding environments, resistant against hospital-grade cleaning solutions, and fluid proof. * Drug library. * Interface: combination of an integrated display and key buttons indicating at least the following parameters and information:   + On/OFF   + Alarms.   + Pumping status.   + Infusion rate.   + Type of syringe.   + Volume infused.   + Volume To Be Infused (VTBI).   + Purge / Bolus.   + Battery status. * Lock function to prevent tampering controls by patients or visitors. * With a security system to prevent dangerous IV medication errors. * Visual and acoustic alarms for at least:   + Occlusion,   + Line occlusion,   + Incorrect size of syringe,   + Drive disengaged,   + Low Battery,   + Power failure,   + VTBI done,   + Malfunction. * Compatible with the follow type and sizes of syringes:   + Type: Single use Luer lock syringes   + Sizes: at least 50ml, 30ml, 20ml, 10ml, 5ml. * Volume infusion range: at least 0.1 ml to 9990 ml. * Delivery Accuracy: ± 2 % * Adjustable bolus rates: in increments of 10 ml/h   + 10ml/h to 150ml/h 5ml syringe,   + 10ml/h to 300ml/h 10ml syringe,   + 10ml/h to 600ml/h 20ml syringe,   + 10ml/h to 900ml/h 30ml syringe,   + 10ml/h to 1200ml/h 50ml syringe, * Keep Vein Open (KVO) rate: 0.1ml/h to 2.5ml/h * Volume To Be Infused (VTBI): 0.1ml to 1000ml, 1min to 24hs.   **Accessories:**   * IV Pole clamp. * Power supply cable. * Mobile IV pole with at least 4 antistatic castors, 2 with brakes, made of steel with anti-corrosive epoxy coating, aluminum, AISI 304 stainless steel or higher quality material.   *NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product during the first 12 months, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included and listed in the offer.* | 6 |
| **Documentation required:**  Bidder shall furnish the following documents:   * Manufacturer brochure or data sheet including at least all technical specifications required. * User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal. * Service manuals must be provided including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits. * List of all common spare parts and accessories with part numbers. * Manufacturer authorization Letter. * Commitment manufacturer letter including:   + installation and commissioning on site would be performed by the manufacturer or his representative in the country (according to the general requirements in the bid document under the clause “Installation and commissioning on site").   + at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause “Warranty").   + at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause “Post-sale Services").   + training on use, cleaning, and disinfecting for the healthcare staff, and basic maintenance for the technical staff, in Ukrainian and English language (according to the general requirements in the bid document under the clause “Training").   **NOTE: All the documents must be submitted in English and Ukrainian language as mandatory. The Russian language could be accepted as an exception to the Ukrainian language.** |  |
| **Regulatory approvals required:**  Bidder shall furnish **documentary evidence** to demonstrate that the good offered is approved according:   * Valid certificate or approval letter from national Ukrainian regulatory body, which confirms local registration of the product and permission to use it in medical practice. * Valid manufacturing licenses. * And at least one of the following regulatory approvals and certificates:   + European Certificate of Conformity (CE) with Regulation 2017/745 or Directive 93/42 EC and Agreement Letter signed with the NB demonstrating the on-going MDR application, for Class IIb devices, or   + FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or   Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan. |  |
| **Safety & product Standards:**  Bidder shall furnish the following documents:   * Valid ISO 13485 certificate. * Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety & regulatory standards:   + IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance   + IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests   + IEC 60601-2-24: Medical electrical equipment - Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers. |  |