SECTION II: Technical Specifications

2.1.Technical Specifications

Item No.	Description and minimum/mandatory specifications
1	**Bed, labour delivery, with accessories** **Specifications:** Bed, labour delivery, with accessories Bed, labour and delivery, 2 sections All sections fit with padded mattresses, entirely detachable from bed for easy cleaning Mattress covers removable via side zipper Transfer bars connect all lower distal portions of the 4 supports, providing maximal structural strength Body section:Mounted on 4 sturdy supports, all finished with height adjustable feet Padded knee crutches are height and width adjustable, set with robust clamps with heavy knob Fixing of the crutch holders is solid steel and welded to the frame of the bed Leg section: Mounted on 4 swivel castors, heavy duty, all 4 with brakes This section can be lowered and recesses entirely under the body section When fully extended, both the body and leg section align to perfectly flat surface Materials: High resistance to corrosion (tropical environment) Frame: epoxy coated tubular steel Adjustable feet:rubber or nylon Sliders/fixtures for the knee crutches: tubular steel, welded to the bed frame Recession track and guiding wheel for the leg section are smoothly finished for easy in/out sliding Mattress: high-density polyurethane foam, density 27-33 kg/m3 Cover: plastic, flexible, highly tear resistant, anti-static, flame retardant, disinfectant- and liquid proof, washable Caster frame/bracket: steel or nylon Caster brake: total-lock type (wheel and rotational lock) Caster wheel: single wheel, mold-on type, non-hooded (for easy maintenance) Wheel bearing: sealed bearing in the swivel and the wheel Swivel is ball-bearing Dimensions: Body section, including mattress: 108-132x72-88x72-88cm (l x w x h) Leg section, including mattress: 63-77x67-82x72-97cm (l x w x h) Frame: 2.7-3.3 cm (outside, across), 1.8-2.2mm (thickness) Swivel castor wheel: 2.7-3.3x9-11cm (w x diameter) Mattresses: 9-11cm (h) Carrying capacity: 135-165kg Knockdown construction: yes Supplied with 1 x complete set of tools required for assembly 2 x leg holders, adjustable height and width 2 x knee crutches, adjustable height and width 2 x knee crutches, adjustable height and width 1 x set fitting removable mattresses, body and leg section List of accessories and parts Detailed step-by-step instructions for assembly and safe use, text-free pictorial based (i.e. line-drawings only) Packaging, labelling, instructions: One (1) unit per box Identify Packaging Standards and provide Packaging Test Reports

	Dimensions: Unit Weight in Kg (including its packaging) Unit Volume in M3 (including its packaging) Dimensions of box, length x width x height in cm Labelling: Compliance with EAN 128 bar code requirements **Treatment regime:**The product is intended for case management in pregnancy consultations, family planning in health facilities and outreach activities in communities. **Target population**: Nurses, doctors, midwifes

2	**General purpose ultrasound system**
	
	Product Description
	A general-purpose system is a device designed to deliver real-time, non-invasive ultrasound imaging that supports a wide variety of probes and related application software packages allowing for the collection, display, and analysis of ultrasound information.
	
	Electrical Requirements:
	● Power requirements according to China standards: 220 VAC, 50 Hz. Power cord with plug type for medical device.
	● Rechargeable batteries with autonomy of at least 30 minutes of continuous use.
	
	Technical specifications:
	● High resolution in real-time mobile ultrasound system.
	● System mounted on stable, mobile trolley fitted with 4 caster antistatic wheels with brakes.
	● Displays images on screen and DICOM.
	● Main Monitor Full HD (at least 21 inch) on articulated arm for easy movements.
	● Control Panel:
	  ● Height adjustment.
	  ● Integrated (at least 12 inch) Full HD LCD touch screen.
	  ● Keyboard.
	  ● Trackball.
	● Support for at least 5 probes.
	● Support for probes cable.
	● Connection ports for at least 4 probes
	● ECG port connection
	● Color thermal printer.
	● USB port at least 2.
	● It must allow networking through Wi-Fi.
	● Battery backup with sleep mode.
	● Measurement accuracy to be better than 2% over 10 cm distance.
	● Doppler display to indicate blood flow both numerically and in color.
	● Ultrasound penetration depth up to 36 cm.
	● The hardware and software included in the offer will allow at least the following clinical application:
	  ● fetal/obstetrics,

	● abdominal (including renal and Gynecology/Pelvic), ● pediatric, ● small organs (chest, testicles, thyroid, etc.), ● neonatal cephalic and, adult cephalic, ● cardiology (adult and pediatric), including - TEE scanning capability. ● peripheral vascular (PV), ● conventional and superficial skeletal muscle, ● transvaginal (TV) and ● transrectal (TR). ● Probes to be included in the offer: all the necessary to cover the aforementioned applications in adult and pediatric patients (Convex, Linear, Phased, TEE, Micro TEE types of probes). ● All materials resistant to hospital-use disinfectants. **Accessories:** ● Paper for color printer, adequate to the printer offered. ● Five (5) tubes of ultrasound coupling gel (5 liters total). ● Stabilizer （稳压器） *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.* **Documentation requirement:** ● User manual must be provided (including operation instructions, maintenance and/or procedures for decontamination, storage conditions, safe disposal). In English and Chinese language. ● Service manual must be provided (including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits). In English and Chinese language. ● List of common spares and accessories with part numbers must be provided. ● Manufacturer authorization. ● 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"). **Regulatory approvals required:** ● National Regulatory Agency/Authority (NRA) requirements compliance, if applicable. ● 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 **documentary evidence** to demonstrate that the good it offers meet the international safety & regulatory standards, providing in addition a signed and dated Declaration of Conformity (DoC) according to ISO 17050 stating compliance to the follow standards: ● ISO 13485: Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes. ● 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 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.
3	**Oxygen Concentrator** **Product Description** Device designed to concentrate oxygen from ambient air and delivers the concentrated oxygen in a controlled manner, up to 5 L/min. IMPORTANT INFORMATION Oxygen concentrators are not suitable to be used as an oxygen source to other medical equipment providing respiratory support, such as ventilators, CPAP devices, High Flow Nasal Oxygen, etc. **Electrical Requirements:** ● Power requirements according to China standards: 220 VAC, 50 Hz. Power cord with plug type for medical device. ● All electrical connection according with the Chinese standards **Technical specifications:** ● Device concentrates oxygen from ambient air. ● System mounted on stable, mobile trolley fitted with 4 caster antistatic wheels with brakes. ● Integrated handle allows for easy moving and positioning. ● Provides continuous flow of concentrated oxygen at least 93% ± 3%, from room air (21%). ● Oxygen sensing device is integrated and measures concentration at the flow meter entrance.

	● Oxygen outlet durable, with approx. 6mm barbed fitting or equivalent
	● Flowmeter range: at least 1 to 5 LPM
	● Flowmeter continuously adjustable with markings at 0.5 L intervals
	● Outlet pressure: 40-70 kPa // 6-10 psi.
	● Continuous monitoring, with visual and audible alert at least for:
	  ● Low/ high output pressure,
	  ● no flow,
	  ● low oxygen concentration < 82%,
	  ● power failure.
	● Sound level produced: less than 52 dB (A)
	● User interface easy to operate with on/off switch and adjustable knob for oxygen percentage.
	● Digital or analogue meter to display cumulative hours of device operation.
	● All materials resistant to hospital-use disinfectants.
	
	Accessories:
	● One (1) power supply cable.
	● Twenty (20) adult cannula, kink-resistant tubing with standard connectors.
	● Twenty (20) infant cannula, kink-resistant tubing with standard connectors.
	● Twenty (20) humidifier cups.
	● Tubing adapter kit, quantity as necessary.
	● Two (2) x Set of spare filters (coarse, pre-filter, inlet filter or as necessary according to the offered devices).
	● Stabilizer （稳压器）
	
	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.
	
	Documentation requirement:
	● User manual must be provided (including operation instructions, maintenance and/or procedures for decontamination, storage conditions, safe disposal). In English and Chinese language.
	● Service manual must be provided (including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits). In English and Chinese language.
	● List of common spares and accessories with part numbers must be provided.
	● Manufacturer authorization.
	● 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").

	Regulatory approvals required:
	● National Regulatory Agency/Authority (NRA) requirements compliance, if applicable.
	● 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 **documentary evidence** to demonstrate that the good it offers meet the international safety & regulatory standards, providing in addition a signed and dated Declaration of Conformity (DoC) according to ISO 17050 stating compliance to the follow standards:
	● ISO 13485: Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes.
	● 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.

4	**Anesthesia workstation with patient ventilator** **Product Description** Device intended for use as an anesthesiology workstation dispensing a mixture of gasses and vapors and varying the proportions to control a patient's level of consciousness and/or analgesia during surgical procedure. Designed for adult and pediatric, over 5 kg weight, patients. **Electrical Requirements:** ● Power requirements according to China standards: 220 VAC, 50 Hz. Power cord with plug type for medical device. ● Built-in rechargeable battery for at least 90 minutes of autonomy. Switch back and forth between battery and mains operation in case of power failures. ● Availability of at least 3 additional sockets for connecting auxiliary equipment (monitor, infusion pump).

	● All electrical connection according with the Chinese standards **Technical specifications:** ● Adult, pediatric, and neonatal patients. ● Electrically driven ventilator, supported by the internal battery in case of power failure. ● Device suitable for low flow anesthesia, closed/semi-closed system. ● Mounted on four (4) antistatic castors at least two of the castors with brakes. ● With a surface/worktable. ● With at least two (2) drawers. ● With a surface or shelf to place a vital signs monitor. ● At least two (2) gas inlets for supply from wall outlets: O_2 and Air. Gas inlet connections according to the requirements of the destination country. With security systems to avoid errors in the gas connection. ● Gas inlet pressure gauges for each gas. ● Provided with a minimum of two (2) gas cylinder yokes for at least O_2 and Air. Gas hose and pressure regulators for O2 and Air cylinders will be accepted. Connections according to the requirements of the destination country. ● Flowmeters for O2, Air and N2O. Minimum range 0.1- 10 L/min. For O2 and N2O, resolution at least 0.05 L/min between 0.1-1.0L/min (electronic flowmeters with the capacity to work with low flows will be accepted). ● Two (2) vaporizer slots, with an interlock system preventing the use of more than one vaporizer simultaneously. ● Safety system that prevents a hypoxic mixture, that guarantees a minimum concentration of 25%. ● With a passive scavenging system ● Self-test ● It must allow emergency start without running the initial tests. ● Oxygen flush ● CO2 absorber canister, reusable, volume of at least 1.2 liters. ● Built-in color display LCD, at least 12”. ● Encoder for adjusting parameters. ● User customization of display options ● Indications and messages on the equipment must be in English and Chinese language. ● All materials resistant to disinfection with hospital-grade products. Ventilator and respiratory system: ● Recirculation system for low-flow anesthesia. ● Breathing system (Circular ventilation circuit) reusable, autoclavable. ● Tidal volume should not depend on variations in fresh gas flow.

	● Circuit compliance and leak compensation. ● Ventilation modes: at least Volume Controlled, Pressure controlled, Synchronized intermittent mandatory ventilation (SIMV), Pressure support (PSV, PS) ● Switching between manual ventilation (MAN/BAG) and automatic ventilation (ventilator). ● Tidal volume delivered range at least: 20 – 1,500 ml. ● Ventilation rate range at least: 5 - 70 bpm. ● Adjustable I/E ratio or adjustable inspiration time. ● Inspiratory pause adjustable. ● Inspiratory pressure range at least: 5 – 60 cm H_2O. ● PEEP range at least: 5 – 25 cm H_2O. ● Peak Inspiratory flow: at least 0 to 120 L/ min. ● Airway Pressure Limiting Valve (APL) for manual ventilation, adjustable. Monitored and Displayed parameters, at least: ● Gas analysis module, at least: O2, CO2, Isoflurane, Sevoflurane, MAC calculation. Display of monitored gas parameters. ● Respiratory rate ● Tidal volume (preferably inspired and expired) ● Minute volume. ● PEEP. ● Plateau pressure. ● Peak pressure ● Medium pressure ● Fraction of Inspired Oxygen ● End-tidal CO_2 (capnography) ● Tree (3) waves vs time: pressure, volume, and flow ● Battery status. ● Alarm settings. Audio and visual alarms for at least: ● Airway pressure. ● Tidal volume ● Minute volume. ● Gas supply failure ● Fraction of Inspired Oxygen ● Apnea. ● Power failure ● Low battery ● System failures **Accessories:** ● Two (2) vaporizers, one for Sevoflurane and one for Isoflurane. With a visual indicator of the filling level of the anesthetic agent, and adapter for filling the vaporizer if required. Full compatibility of the vaporizer model offered with the anesthesia machine model offered. If a vaporizer from another manufacturer is offered, official confirmation from the respiratory and anesthesia device

	manufacturer of the full compatibility of the declared vaporizer must be provided. ● One (1) Air pressure regulator for supply from the wall outlet, compatible with the medical gas system of the health unit. ● One (1) O2 pressure regulator for supply from wall outlet, compatible with the medical gas system of the health unit. ● Hoses for Air and O2 with their respective connections compatible with the gas inlet of the equipment and the supplied pressure regulators. ● Twenty (20) complete consumable kits for the gas analyzer module. ● Twenty (20) Pediatric disposable breathing circuits complete (including reservoir bag) ● Twenty (20) Adult disposable breathing circuits complete (including reservoir bag) ● One (1) Oxygen cell, if applicable. ● Two (2) Flow sensors, if applicable. ● One-piece transparent mask (included), for adults and children, 2 pieces of each size. ● Breathing filters 20 pieces ● Soda lime, color-changing: 10kg ● Stabilizer （稳压器） *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.* **Documentation requirement:** ● User manual must be provided (including operation instructions, maintenance and/or procedures for decontamination, storage conditions, safe disposal). In English and Chinese language. ● Service manual must be provided (including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits). In English and Chinese language. ● List of common spares and accessories with part numbers must be provided. ● Manufacturer authorization. ● 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"). **Regulatory approvals required:** ● National Regulatory Agency/Authority (NRA) requirements compliance, if applicable. ● 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 **documentary evidence** to demonstrate that the good it offers meet the international safety & regulatory standards, providing in addition a signed and dated Declaration of Conformity (DoC) according to ISO 17050 stating compliance to the follow standards: ● ISO 13485: Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes. ● 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 60601-2-13: Particular requirements for the safety of anesthetic workstations.