SECTION II: Technical Specifications and Schedule of Requirements

2.1.Technical Specifications

LOT 1 Medical Equipment

1. Operating table with accessories

NAME, CATEGORY AND CODING		Required Specification
1	Generic name	Operating table with accessories
2	Specific type or variation (optional)	Electrohydraulic
3	GMDN/UMDNS definition	A mobile, mains electricity (AC-powered) hydraulic-mechanism table designed to be adjusted to support a patient during many types of surgical interventions. The table surface consists of many articulated sections that can be elevated or lowered for contouring to accommodate numerous anatomical positions (e.g., the whole table top may be adjusted to form a curved surface) to satisfy the requirements of many clinical specialties.
PURPOSE OF USE		
4	Clinical or other purpose	be adjusted to support a patient during many types of surgical interventions.
5	Level of use (if relevant)	District and city level maternity house, perinatal centre
6	Clinical department/ward (if relevant)	operating theatre of maternity house
TECHNICAL CHARACTERISTICS		

7	Detailed requirements	Frame material: stainless steel 316/316L Electro-hydraulic with electronic control for positions. At least 5 articulated sections: head, back, pelvis and 2 separate legs sections. Minimum overall table dimensions: 180 cm long x 60 cm wide. Must accommodate patients up to at least 200 kg in all operating positions. Lateral bars all along the table to hook for surgical accessories. Supports patient during operating procedures: ● Separate movement of head, torso and legs. ● Table rotation up to 180 degrees. ● Overall height adjustment for ease of user access. ● Vertical displacement ● Trendelenburg at least ±30 deg and reverse Trendelenburg positions -15 deg. ● Right and Left lateral tilts: at least +18º right/-18º left ● Vertical height movement range to include 70 cm to 110 cm from floor ● Longitudinal displacement regulation range of at least of 25 cm ● Controllable global movements to include up/down, forward/back, left/right and individual movements to allow at least head +20 deg, leg raise/lower +20 / -90 deg; lateral tilt range at least +18º right/-18º left. All the functions available in manual mode in case of power interrupt. Include Foot control.
PHYSICAL/CHEMICAL CHARACTERISTICS		
8	Components	Supplied with two armrests at least 0.4m long, that fit adjustable positions on each side of table. Supplied with removable or foldable side restraints on each side of table Supplied with two leg slings and two vertical supports for leg slings Leg section of table to be removable to allow lithotomy position Supplied with padded mattress, in sections that match layout of table sections All exposed metal parts to be constructed of stainless steel All non-metal parts to be constructed of durable, waterproof, washable and antistatic material Easy access to filters and oil sumps required for on-site maintenance . Removable mattress covering antistatic, impermeable, washable, material. Mattress covering in fire extinguishers material, resistant to corrosion, water, detergent soap, 70% ethylic alcohol solution with or without nitrite and to the hypochlorite of sodium.
9	Mobility, portability(if relevant)	Mobile
UTILITY REQUIREMENTS		
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		

10	Accessories (if relevant)	Leg slings / supports as specified in the components section 2 stainless steel foot support; 2 stainless steel hands support; 2 stainless steel feet supports separable with cushion; 1 stainless steel head support; 1 stainless steel shoulder support; 2 stainless steel wrist support o support for extended arm; 2 feet belts; 1 stainless steel support for hand operation; 1 autoclave sterilizable basin; 1 cushion for back support; 1 Telescopic stainless steel dismountable intravenous support system.
11	Consumables / reagents (if relevant)	Oil and replacement filters sufficient for two years' daily use
12	Packaging & Labelling:	Symbols used according ISO 15223. Manufacturer's product code or reference number. Manufacturer identification. Address of the manufacturing site. Stored Conditions.
ENVIRONMENTAL REQUIREMENTS		
13	Context-dependent requirements	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 90% at 30 °C Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 90% at 30 °C
TRAINING, INSTALLATION AND UTILISATION		
15	Pre-installation requirements (if relevant)	Supplier to provide details of all other available fittings with specifications and costs. Supplier to perform installation, safety and operation checks before handover
16	Requirements for commissioning (if relevant)	Local clinical staff to affirm completion of installation
17	Training of user/s (if relevant)	Training of users in operation and basic maintenance shall be provided
17	User care(if relevant)	Cleanable with sanitizing solution for hospital environment use.
WARRANTY AND MAINTENANCE		
18	Warranty	Minimum 12 months
19	Type of service contract	The equipment must be new, not used, produced not earlier than 2019
DOCUMENTATION		
20	Documentation requirements	User Manual, Service Manual. Russian and English languages. To include: ● Cleaning procedure ● Safe disposal instructions ● Calibration Procedure and Routine Maintenance. ● List to be provided of important spares and accessories, with their part numbers and cost. ● List to be provided of important spares and accessories, with their part numbers and cost.
DECOMMISSIONING		
21	Estimated Life Span	At least 10 years
SAFETY AND STANDARDS		
22	Risk Classification	Class I (GHTF Rule 1);Class I (USA); Class I (EU, Japan, Canada and Australia)

23	Regulatory Approval / Certification	Must be FDA, CE approved product.
24	International standards	Quality Management Certifications ISO 9001 ISO 13485:2016 Environment Certifications ISO 14001 and ISO 50001 are desirable ISO 14971: 2012 Technical Certifications: IEC 60601-1-1:2012 IEC 60601-1-2: 2015 IEC 60601-2-46 Ed. 2.0:2010 (b) (2014 desirable)

2. Capnograph

NAME, CATEGORY AND CODING		Required Specification
1	Generic name	Capnograph
PURPOSE OF USE		
2	Clinical or other purpose	The capnograph is designed to monitor CO2 on the exhale, respiration rate, functional oxygen saturation of the blood and pulse rate in the observation mode - assisted ventilation, emergency care and anesthesia. The capnograph includes a miniature vacuum pump for removing the exhaled respiratory mixture using an airway adapter for sampling and a nasal cannula. Capnograph for monitoring patients of various age groups - adults, children, newborns.
3	Level of use (if relevant)	District hospital, Provincial hospital, Specialized hospital
4	Clinical department/ward(if relevant)	In institutions where there is reanimation, and intensive care units, operating rooms with the need for respiratory therapy
5	Overview of functional requirements	The method of infrared optical capnometry is based on the ability of asymmetric gas molecules (carbon dioxide — CO2, nitrous oxide — N2O, water vapor — H2O) to absorb infrared radiation. Gas analyzers working on this principle are also called direct flow capnographs, since the sensor (measuring chamber) for measuring the CO2 concentration is installed directly in the respiratory circuit, between the endotracheal tube and the circuit tee, and the CO2 concentration is measured at the point of contact between the sensor and the respiratory mixture.
TECHNICAL CHARACTERISTICS		
6	Detailed requirements	The capnograph includes a miniature vacuum pump for removing the exhaled respiratory mixture using an airway adapter for sampling and a nasal cannula. Direct flow sensor. Absorption of single-beam unscattered infrared radiation. CO2 - Range 0-150 mmHg 0-19.7%, 0-20 kPa. Accuracy: ± 2 mmHg (0-40 mm Hg) ± 5% of reading (41-70 mm Hg) ± 8% of reading (70-150 mm Hg) Response time 60 ms resolution: 1 mm Hg .art. Units: mm Hg, kPa or %. Respiratory rate: Range: 0 to 150 breaths / min. Measurement accuracy: ± 1 breath /min. Resolution: 1 breath / min
7	Displayed parameters	The display shows the concentration of CO2.
WARRANTY AND MAINTENANCE		
8	Warranty	Minimum 12 months

9	Type of service contract	The equipment must be new, not used, produced not earlier than 2019
DOCUMENTATION		
10	Documentation requirements	User Manual, Service Manual. Russian and Eglish languages. To include: ● Cleaning procedure ● Safe disposal instructions ● Calibration Procedure and Routine Maintenance. ● List to be provided of important spares and accessories
11	Packaging & Labelling:	Symbols used according ISO 15223. Manufacturer's product code or reference number. Manufacturer identification. Address of the manufacturing site. Stored Conditions.
SAFETY AND STANDARDS		
12	International standards	Quality Management Certifications ISO 9001 ISO 13485:2016 Environment Certifications ISO 14001 and ISO 50001 are desirable Technical Certifications ● ISO 60601-1:2012 ● IEC 60601-1-1 2001 ● IEC 60601-1-2:2015 ● ISO 80601-2-55:2018

3. Doppler Ultrasound machine

NAME, CATEGORY AND CODING		Required Specification
1	Generic name	Doppler ultrasound machine
3	Alternative name/s (optional)	Diagnostic imaging equipment, dopplerometry, ultrasound scanning, ultrasound, ultrasound diagnostics
4	GMDN/UMDNS definition (optional)	An assembly of devices designed to be used in a wide variety of both extracorporeal and/or intracorporeal (endosonography or endoscopic) ultrasound imaging procedures. A general-purpose system supports a wide variety of transducers and related application software packages allowing for the collection, display and analysis of ultrasound information.
PURPOSE OF USE		
5	Clinical or other purpose	For use in a wide variety of both extracorporeal and/or intracorporeal ultrasound imaging procedures in order to anatomical analysis and flux measurements. Usages are : Abdominal organs Pediatrics and Neonatology Superficially located organs and structures Musculoskeletal system, Urology, Cardiology Angiology, Neurology
6	Level of use (if relevant)	medical center, specialized institutions, maternity hospitals, gynecological hospitals, children's hospital, perinatal centers, obstetric hospitals of all levels
7	Clinical department/ward(if relevant)	District, city maternity hospitals. Perinatal center, women's consultations

8	Overview of functional requirements	Displays images on integral screen and enables DICOM compliant image transfer. Supplied with all necessary probes for cardiac, vascular, obs / gyn, prostate and breast imaging, with colour Doppler imaging, for patients of all ages.
TECHNICAL CHARACTERISTICS		
9	Detailed requirements	Features and Scan Modes: ● B-mode, M-mode ● Color Doppler mapping, tissue Doppler, pulse-wave Doppler mode ● Blood flow visualization (B-Flow) ● Doppler mode, Multi-beam composite scan (CRI), 3D and 4D modes. ● Real-time, non-invasive imaging (organ structures and functionality) ● Displays images on screen and DICOM. ● 4D mode (up to 47 3D images per second), including tomographic ultrasound mode - TUI ● Multifocal signal processing - FFC ● High Sensitive Doppler - HD-Flow ● Patient data management system and programmable ready-made sets of settings by the use. ● Data transmission over the network in DICOM 3 format ● Constant-wave Doppler mode ● Ultrasound penetration depth up to 36 cm ● Ultrasonic beamforming fully digital ● Dynamic range 274 dB ● Maximum frame rate 700 ● Panoramic Scanning - XTD View ● Grain Suppression Mode - SRI ● 3D Program and Inversion Mode (with specialized sensors) ● Coded pulse transmission - CE ● Patient data management system and programmable ready-made sets of settings by the user Display Parameters ● Color touch screen 10.4” ● Monitor 19 " High resolution LCD monitor ● Unit display to be at least 512 by 512 pixels, with at least 256 gray scale levels and 256 color scale levels. ● Area, distance, volume, angles, speed and acceleration. ● Frozen image zoom of at least 10X. ● Dynamic real time zoom of at least 4X
10	Displayed parameters	Unit display to be at least 512 by 512 pixels, with at least 256 gray scale levels and 256 color scale levels. Area, distance, volume, angles, speed and acceleration. Frozen image zoom of at least 10X. Dynamic real time zoom of at least 4X..
11	User adjustable settings	* Adjustable depth gain, freeze frame and image zoom facilities required. * Protocols. * Cine record and playback feature required, with frame rate at least 500 fps. * Measurement accuracy to be better than 2% over 10cm distance. * Alphanumeric annotation to be possible
PHYSICAL/CHEMICAL CHARACTERISTICS		

12	Components(if relevant)	Unit to be supplied on stable, mobile trolley fitted with 4 wheels that can be braked Display to have tilt/swivel facility for easy viewing Configurable footswitch control with at least 2m lead required Probe leads to be at least 1.5m in length Trolley to include shelf space for image printer and documentation
13	Mobility, portability(if relevant)	Unit to be supplied on stable, mobile trolley fitted with wheels that can be braked
14	Raw Materials(if relevant)	N/A
UTILITY REQUIREMENTS		
15	Electrical, water and/or gas supply (if relevant)	110-220 V, 60-50 Hz UPS to allow operation at ± 30% of local rated voltage and one hour operation in the event of mains power failure. Electrical protection by resettable circuit breakers in both live and neutral supply lines. Mains supply cable to be at least 3m in length.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
16	Accessories (if relevant)	Sensors: Multi-frequency, broadband high-density electronic: *Convex (including matrix, 2 - 5 MHz, 2 - 8 MHz, 2 - 6 MHz) * Linear (including matrix, 4 - 10 MHz, 7 - 18 MHz, 3 - 8 MHz, 4 - 13 MHz) *Phased (1 - 5 MHz, 4 - 10 MHz) *Microconvex intra-cavity (4 - 9 MHz) Sensors for receiving static three-dimensional images and volumetric images in real time (including matrix): *Convex (2 - 8 MHz, 3 - 9 MHz, 1 - 4 MHz) *Microconvex intracavitary (4 - 9 MHz, 5 - 13 MHz, 4 - 10 MHz) *Linear (6 - 18 MHz) Supplied with all necessary probes for cardiac, vascular, obs / gyn, prostate and breast imaging, with colour Doppler imaging: Adult and Pediatric
17	Sterilization process for accessories (if relevant)	Low temperature sterilization for probes (if required)
18	Consumables / reagents (if relevant)	Printer paper Gel Disposable covers for endocavity probe
19	Spare parts (if relevant)	Medical units select them according to their needs, ensuring compatibility with the brand and model of the medical device.
20	Packaging & Labelling:	Symbols used according ISO 15223. Manufacturer's product code or reference number. Manufacturer identification. Address of the manufacturing site. Stored Conditions.
PACKAGING		
ENVIRONMENTAL REQUIREMENTS		
21	Context-dependent requirements	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 90% at 30 °C. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 90% at 30 °C.
TRAINING, INSTALLATION AND UTILISATION		

22	Requirements for commissioning (if relevant)	Supplier to perform installation, safety and operation checks before handover Local clinical staff to affirm completion of installation
23	Training of user/s (if relevant)	Training of users in operation and basic maintenance shall be provided Advanced maintenance tasks required shall be documented
24	User care(if relevant)	Unit layout to enable easy cleaning and sterilization of all surfaces
WARRANTY AND MAINTENANCE		
25	Warranty	Minimum 12 months
26	Type of service contract	The equipment must be new, not used, produced not earlier than 2019
27	Spare parts availability post-warranty	5 years
28	Software / Hardware upgrade availability	Clinical/operational software upgrade available during useful lifespan with DICOM Support and licences if necessary.
DOCUMENTATION		
29	Documentation requirements	● List to be provided of equipment and procedures required for local calibration and routine maintenance ● List to be provided of important spares and accessories, with their part numbers and cost. User Manual, Service Manual. Russian and English languages. To include: ● Cleaning procedure ● Safe disposal instructions ● Calibration Procedure and Routine Maintenance. ● List to be provided of important spares and accessories, with their part numbers and cost.
DECOMMISSIONING		
30	Estimated Life Span	At least 10 years
SAFETY AND STANDARDS		
31	Risk Classification	Class B (GHTF Rule 10); Class II (USA); Class II (EU, Japan, Canada and Australia)
32	International standards	Quality Management Certifications ISO 9001 ISO 13485:2016 Environment Certifications ISO 14001 and ISO 50001 are desirable ISO 14971: 2012 IEC 60601-1:2012 IEC 60601-1-1:2001 IEC 60601-1-2::2015 IEC 60601-2-37::2015 IEC 61391-1:2017 IEC 61391-2:2010 IEC 62359 :2017

4. Electrocoagulation Equipment

NAME, CATEGORY AND CODING		Required Specification
1	Generic name	Electrosurgical units/ Electrocoagulation Equipment

2	GMDN/UMDNS definition (optional)	An assembly of devices that uses high frequency electrical energy in a radio-frequency (RF) band to develop heat directly within soft-tissue cells (thermodynamic) for cutting and coagulating tissue typically during general surgical procedures. Tissue resistance to the electrical current creates the heat as the current travels through the body between electrodes. The assembly typically includes an energy-producing generator with monitoring functions, a single-use/reusable handpiece with electrodes to apply the energy to the surgical site, connecting cables, and a foot-switch as an option to regulate the energy.
PURPOSE OF USE		
3	Clinical or other purpose	Use high frequency electrical energy in a radio-frequency (RF) band to develop heat directly within soft-tissue cells (thermodynamic) for cutting and coagulating tissue typically during general surgical procedures
4	Level of use (if relevant)	City hospital, district hospital, provincial hospital, specialized hospital, maternity hospitals, perinatal center
5	Clinical department/ward(if relevant)	Operating room , during surgery, mayal surgery
6	Overview of functional requirements	Allows cutting of tissue and coagulation of blood during surgery using high frequency electrical current Allows both monopolar and bipolar operation Adjustable power level can be set by the operator
TECHNICAL CHARACTERISTICS		
9	Detailed requirements	Modes of operation to include pure cut, pure coagulation and blended (combined) Operation to be controlled by foot pedal, with minimum 2m connection cable, and also by handswitch on probe RF generator to be within the range 300 to 1000 kHz, output to be electrically isolated from ground. Monopolar maximum power to be at least 350W (cut) and 200W (coagulate) Bipolar maximum power to be at least 50 W (coagulate) Visual and audible activation indicators required Visual and audible cable disconnection alarm required Display and keyboard for all parameters visualization and setting. Power control in the main panel. Coagulation: high power for contact coagulation current with high crest factor for spray coagulation. Memory for at least 10 programs with their waveforms and power levels.18) Monitoring system of the electrode-patient connection of at least 1 Khz measurement frequency. Automatic power tuning with dynamic control and automatic stop in case of any working problem. Protection against defibrillator discharges. Convection refrigeration without ventilator. Minimum nominal high frequency output powers for cutting: a) monopolar 300 W at 500 ohms; b) bipolar 100 W at 500 ohms. Minimum nominal high frequency output powers for coagulation: a) bipolar 100 W at 125 ohms; b) monopolar spray 100 W at 500 ohms; c) monopolar forced 120 W at 350 ohms.
10	Displayed parameters	power settings and alarms
11	User adjustable settings	user settings and alarms
PHYSICAL/CHEMICAL CHARACTERISTICS		

12	Components(if relevant)	compact design
13	Mobility, portability(if relevant)	Portable
UTILITY REQUIREMENTS		
14	Electrical, water and/or gas supply (if relevant)	110-220 V/ 50-60 Hz Electrical protection by resettable circuit breakers in both live and neutral supply lines. Compliance with national electrical standards and regulations.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
15	Accessories	Mandatory (Two sets of spare fuses (if replaceable fuses used) Supplied with two reusable, sterilizable, monopolar patient plates with minimum 2m long connection cable Supplied with two each of reusable, sterilizable, monopolar and bipolar probe with selection of tip sizes for each; pencils, ball electrodes, loop electrodes, reusable return electrodes, coagulators, adapters and blade electrodes monopolar pedal , bipolar pedal
17	Sterilization process for accessories	Mandatory
18	Consumables / reagents	Disposable plates two areas. Connection cable for plates. Pencils with cable. Removable Electrodes: ball, knife, needle and handle. pencil set with its own reusable monopolar active cable that includes a removable blade electrode, activated carbon filter to remove odors and toxic gases.
19	Spare parts	Specific spare parts to consider in the maintenance of 2 years.
PACKAGING		
20	Sterility status on delivery	Yes
21	Shelf life (if relevant)	At least 10 years
TRAINING, INSTALLATION AND UTILISATION		
22	Training of user/s (if relevant)	Yes
23	User care(if relevant)	Cleanable with sanitizing solution for hospital environment use.
WARRANTY AND MAINTENANCE		
24	Warranty	Minimum 12 months
25	Maintenance tasks	Preventive periodical maintenance
26	Type of service contract	The equipment must be new, not used, produced not earlier than 2019
27	Spare parts availability post-warranty	Must be available
28	Software / Hardware upgrade availability	Is a Must
DOCUMENTATION		
29	Documentation requirements	• List to be provided of equipment and procedures required for local calibration and routine maintenance • List to be provided of important spares and accessories, with their part numbers and cost. User Manual, Service Manual. Russian and English languages.

		To include: ● Cleaning procedure ● Safe disposal instructions ● Calibration Procedure and Routine Maintenance. ● List to be provided of important spares and accessories, with their part numbers and cost.
DECOMMISSIONING		
30	Estimated Life Span	At least 10 years
SAFETY AND STANDARDS		
31	Risk Classification	Class B (GHTF Rule 9); Class II (USA); Class II (EU, Japan, Canada and Australia)
32	International standards	Quality Management Certifications ISO 9001 ISO 13485:2016 Environment Certifications ISO 14001 and ISO 50001 are desirable ISO 14971:2012 IEC 60601-1:2012 IEC 60601-1-1:2001 IEC 60601-1-2::2015 IIEC 60601-2-2 Ed. 5.0:2009

5. Obstetric table/Bed for delivery

NAME, CATEGORY AND CODING		Required Specification
1	Generic name	Obstetrical table
2	Specific type or variation (optional)	line-powered
3	Alternative name/s (optional)	Table, obstetric (and accessory); Table, obstetrical, AC-powered (and accessory); Birthing table
4	GMDN/UMDNS definition (optional)	A mains electricity (AC-powered), adjustable table designed to support a woman's body in an appropriate position during labour and delivery and in other examination/treatment procedures related to pregnancy. This device will typically include, e.g., a motorized raise/lower function, leg holders (stirrups), traction handles, a receptacle for afterbirth and wheels for transport to the various birthing rooms.
PURPOSE OF USE		
5	Clinical or other purpose	Designed to support a woman's body in an appropriate position during labour and delivery and in other examination/treatment procedures related to pregnancy.
6	Level of use (if relevant)	Health post, health centre, district hospital, provincial hospital, specialized hospital.
7	Clinical department/ward(if relevant)	gynaecology department

8	Overview of functional requirements	Supports patient during labour and delivery. Allows separate movement of head, torso and legs. Allows overall height adjustment for ease of user access. Use of table for X-ray / fluoroscopy is not required. Leg section removable when necessary.
TECHNICAL CHARACTERISTICS		
9	Detailed requirements	Electro-hydraulic functioning with electronic control for positions. Must accommodate patients up to at least 190 kg. All movements must be motorized and easily controlled. Vertical height movement range to include 0.65 to 1.0 m from floor level. Controllable global movements to include up/down and Trendelenburg at least ±30 deg. Individual movements to allow at least head +20 deg, leg raise/lower +20 / -90 deg. Control panel and remote control. With dual-sided pedal control. Manual emergency movement and reset. Head and lower ends: easily removable (for resuscitation).
PHYSICAL/CHEMICAL CHARACTERISTICS		

10	Components(if relevant)	Minimum overall table dimensions: 180 cm long x 60 cm wide. Supplied with two armrests at least 40 cm long, that fit adjustable positions on each side of table. Supplied with two leg slings, two vertical supports for leg slings and two knee supports. Supplied with removable or foldable side restraints on each side of table. Leg section of table to be removable to allow lithotomy position. Removable handles on each side must be securely fastened for patient traction. Supplied with removable stainless steel bowl, mounted for afterbirth collection. All exposed metal parts to be constructed of stainless steel 316/316L. All non-metal parts to be constructed of durable, waterproof, washable and antistatic material. Mounted on castors of minimum diameter 12 cm, with braking facility on each castor. The top of the bed shall be in 3 sections. Ratchet operated rising backrest, retractable foot end and a fixed centre part. Three separate mattresses of at least 100 mm thickness for each section fixed in.
11	Mobility, portability(if relevant)	Mounted on four castor wheels, two with brake.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
12	Accessories (if relevant)	Pair of adjustable leg crutches with anti-static pads. Liquid collection pan.
13	Packaging & Labelling:	Symbols used according ISO 15223. Manufacturer's product code or reference number. Manufacturer identification. Address of the manufacturing site. Stored Conditions.
UTILITY REQUIREMENTS		
14	Electrical, water and/or gas supply (if relevant)	110-220 V, 60-50 Hz. Power input to be fitted with compatible mains plug, Voltage corrector / stabilizer to allow operation at ± 30% of local rated voltage. Manual operation to be possible in the event of power failure. Electrical protection by resettable overcurrent breakers or replaceable fuses, fitted in both live and neutral, Main power supply off switch to be fitted at least 3m from table. Compliance with local electrical standards and regulations.
15	Context-dependent requirements	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 90% at 30 °C. Capable of operating continuously in ambient temperature of 10 to 40 °C and relative humidity of 90% at 30°C.
TRAINING, INSTALLATION AND UTILISATION		
16	Pre-installation requirements(if relevant)	Supplier to perform installation, safety and operation checks before handover. Local clinical staff to affirm completion of installation
17	Training of user/s (if relevant)	Training of users in operation and basic maintenance shall be provided
18	User care(if relevant)	Cleanable with sanitizing solution for hospital environment use.
WARRANTY AND MAINTENANCE		
19	Warranty	Minimum 12 months from the date of commissioning.
20	Maintenance tasks	Replacement oil or grease sufficient for two years' maintenance.
21	Type of service contract	The equipment must be new, not used, produced not earlier than 2019

DOCUMENTATION		
22	Documentation requirements	Advanced maintenance tasks required shall be documented. User Manual, Service Manual. Russian and English languages. To include: ● Cleaning procedure ● Safe disposal instructions ● Calibration Procedure and Routine Maintenance. ● List to be provided of important spares and accessories with their part numbers and cost.
DECOMMISSIONING		
23	Estimated Life Span	At least 10 years
SAFETY AND STANDARDS		
24	Risk Classification	Class A (GHTF Rule 12);Class II (USA); Class I (EU, Japan, Canada and Australia)
25	Regulatory Approval / Certification	Must be FDA, CE approved product.
26	International standards	Quality Management Certifications ISO 9001 ISO 13485:2016 Environment Certifications ISO 14001 and ISO 50001 are desirable ISO 14971:2012 IEC 60601-1:2012 IEC 60601-1-1:2001 IEC 60601-1-2::2015

LOT 2 Medical Furniture

Item N°	Product Name	Product Description
1	Medical Examination Couch	Couch is designed to equip the treatment room and dressing room for examination of pregnant and postpartum women, nursing stations. Overall dimensions must be not less than: Length not less than - 1800 mm Width not less than - 500 mm Height not less than - 500 mm It should have movable and detachable leg support accessories for women examination. The frame or equivalent is a square steel pipe. The thickness of the profile pipe is not less than 1.2 mm The presence of a headrest - is Headrest - no cutout Headrest angle - from 0 ° to 45 °. Upholstery - Synthetic Leather-Should have high hygienic properties: air and steam permeability, hygroscopicity, eco friendliness, wear resistance, which allows multiple treatment with medical disinfectants and detergents. Color - pastel colors Manufacturer certification: ISO 9001, ISO 13485 or equivalent local GMP certification is acceptable Labels and symbols should be designed under ISO 15223 standard.
2	Stool (rotating)	The stool is designed to equip the delivery room and small operating room. All metal parts must be made of stainless steel. The chair must have a stable base, equipped with 5 swivel wheels Ø50mm, two of which with a brake. Ability to adjust the height of the seat relative to the floor.

		360-degree rotation node. Adjustable in height using a screw system. Diameter of the five-beam base, at least 540 mm • Diameter of a seat, not less than 370 mm • Range of adjustment of height of a seat of a chair, mm 440-640 mm • Mass of a chair, no more than 15 kg • Maximum load 120 kg The product should be a welded metal structure on a beam support with soft elements on the seat The stool should consist of a base, stand and seat with or without backrest. There can be a special ring - footrest. The base of the seat should be upholstered in artificial leather with a foam flooring. The material used for upholstery should have high hygienic properties: air and steam permeability, hygroscopicity, eco friendliness, wear resistance, which allows multiple treatment with medical disinfectants and detergents.
3	Manipulation table	A manipulation table with two shelves is intended for placement and delivery of instruments, materials, medicines, devices in medical institutions. Smooth, convenient rolling of the table should be ensured by rotary rubberized wheel bearings with a diameter of 80 mm, two of which with a brake, and a reliable side handle. Shelves with profiled four-sided flanging and the presence of a lower shelf guard protect medicines and instruments from accidental falling. Design features: • the frame of the table should be made of a stainless steel profile of rectangular cross section, the shelves should be made of stainless steel; • the shelves of the table should have a profiled four-sided flanging that protects the instruments from accidental fall; • The outer surfaces of the table must be resistant to non-chlorine-based disinfectants used, convenient for sanitization in clinical environment. Specifications: Dimensions: • length (with handle) not less than 720 mm • width (on wheels) not less than 460 mm • height not less than 800 mm Shelf Dimensions: • length not less than 630 mm • width not less than 430 mm • Weight, no more than 15 kg Total distribution load on the table, not less than 20 kg Manufacturer certification: ISO 9001, ISO 13485 or equivalent local GMP certification is acceptable
4	Instrument Cabinet	It is for storing medicines, instruments, hospital documents, patient cards in medical institutions and organizations. Chrome-plated magnetic latches lock the door in a closed state (installed on glass doors). Material: stainless steel or another metallic material coated with anti-static and washable material The maximum load on a metal shelf is at least 30 kg, on a glass shelf - at least 10 kg. External dimensions, mm (HxWxD): not less than 1655x700x320 Type of coating - hygienically safe, corrosion-resistant powder Manufacturer certification: ISO 9001, ISO 13485 or equivalent local GMP certification is acceptable
5	Patient carrying Trolley	The medical trolley for transporting patients is intended for transporting patients inside medical institutions: in reception departments, to operating rooms, intensive care units, and other departments of a medical institution. The trolley is height-adjustable using a hydraulic jack with a foot pedal. Folding side rails. Steeples regulation of the position of the back section by means of a pneumatic spring. Four resistant polyurethane or similar rubberized wheels, two at least with breaks. Diameter not less than 200mm. The swivel castors and wheels should comply the ISO 22882 standard for safety and performance Length, not less than 2100 mm Width, not less than 700 mm

		Mattress dimensions: Length, not less than 1885 mm Width, not less than 600 mm Thickness, not less than 80 mm. Panel height adjustment range, not less than 555 ... 880 mm Height range along fences, not less than 695 ... 1020 mm. The angle of elevation of the back section of the panel is 0º ... 60º The weight of the trolley is not more than 90 kg Load capacity is at least 150kg. Upholstery - Washable, high hygienic properties, water resistant, wear resistance, which allows multiple treatment with medical disinfectants and detergents. Manufacturer certification: ISO 9001, ISO 13485 or equivalent local GMP certification is acceptable Labels and symbols should be designed under ISO 15223 standard
6	Anaesthesiologist table	Designed for the work of an anesthetist during surgery. Material: stainless steel. (tabletop), the rest can be made of stainless steel or other metallic or metallic coated, durable, resistant to disinfectant and anti-bacteria material e.g. non-chlorine-based aldehyde-based disinfectants used, convenient for sanitization. Complete set: 4 drawers, 1-hinged door, 2 internal regiments, tabletop with rim, handle for a possibility of movement. Mounted on four at least 50 mm antistatic castors two with brakes. Rim in 4 sides of tabletop height not less than 16 mm and no more than 20 mm Overall dimensions not less than 900x600x900 mm. Table weight no more than 80 kg. Overall dimensions of drawers (WxDxH): - top not less than 340x530x125 mm; - lower: not less than 340x530x150 mm. Internal shelves are retractable and removable. Drawers on ball guides, full extension, removable. Manufacturer certification: ISO 9001, ISO 13485 or equivalent local GMP certification is acceptable
7	Mobile surgical instrument table	Medical instrumental table is designed to accommodate instruments, devices and other medical supplies used in medical procedures and surgical operations. The design of the base and the swivel-working surface should be convenient for the operation of the operating team. The height of the table must be adjusted with a hydraulic jack using the foot pedal. The rotation of the working surface is done manually with fixation with a screw clamp. The table should have rotary rubberized wheel bearings Ø80 mm, two of which with a brake. Design features: • the table should be made of stainless steel; • the working surface must have a flange on four sides; • the outer surfaces of the table must be resistant to any non-chlorine-based aldehyde-based disinfectants used, convenient for sanitization. Specifications: • Overall dimensions: Not less than 540x795x920 mm; Possibility of turning the shelf to any angle in the horizontal plane. Possibility of manual adjustment in height: not less than 1350 mm Internal shelf size: Not less than 740x510 Rated load on the table: Not less than 10 kg. Wheels: At least 4 wheels on swivel brackets, self-orientating, of non-marking rubber, two wheels must be with an autonomous brake device. Barriers: Not less than 16 mm and no more than 20 mm. Shelf: One removable shelf from sheet metal with a thickness (stainless steel) of at least 0.8 mm. The table frame is an all-welded construction (with complete sealing of welds) made of stainless steel pipe. The total permissible load on the table: 10 kg • Table weight: no more than 25 kg
8	IV infusion stand	Designed for hanging at a certain height vials or single-use systems with medicinal solutions during medical procedures. Rack: Stable metal pipe of circular cross section; Base: five-beam base with rubber or plastic plugs; Base diameter: not less than 600 mm Material: stainless steel or chrome-plated steel. A cross on five supports (5 legs (aluminium) on swivel castors wheels with a diameter of 50 mm), the upper part with 4 hooks, an adjustable height of 1300-2120 cmm, should be the capacity of the drip catcher. The rated load on one hook is at least 2 kg. Manufacturer certification: ISO 9001, ISO 13485 or equivalent local GMP certification is acceptable

LOT 3 Surgical Instruments

1	Hemostatic forceps 1x2 teeth , straight	Product Description: Hemostatic forceps, 1x2 teeth, Straight, used for haemostasis. length - not less than 160 mm, Material: Martensitic stainless steel (quenched, magnetic steel) composition: 0.20% carbon; 13% chromium. Highly impact resistant. Instructions for use: Used for haemostasis. Hemostatic forceps are used to compress blood vessels or other tubular structures to obstruct the flow of blood or fluids. This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging & Labelling: Unit presentation: forceps single unit, in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
2	Hemostatic forceps toothed , curved	Product Description: Hemostatic forceps, Curved, Toothed, used for haemostasis. Length: not less than 160mm. Working part length: not less than 45 mm. bending height: not less than 10 mm.

		Material: Martensitic stainless steel (quenched, magnetic steel) composition: 0.20% carbon; 13% chromium. Highly impact resistant. Instructions for use: Hemostatic forceps, used for haemostasis. Hemostatic Forceps can be used to clamp large blood vessels, manipulate heavy tissue, and dissect soft tissue. This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging & Labelling: Unit presentation: forceps single unit, in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
3	Hemostatic forceps toothed , straight	Product Description: Hemostatic forceps, Straight. Toothed. used for haemostasis. Length: not less than 160mm. Working part width: not less than 2mm. Material: Martensitic stainless steel (quenched, magnetic steel) composition: 0.20% carbon; 13% chromium. Highly impact resistant.

		Instructions for use: Hemostatic forceps, used for haemostasis. Hemostatic Forceps can be used to clamp large blood vessels, manipulate heavy tissue, and dissect soft tissue. This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging & Labelling: Unit presentation: forceps single unit, in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
4	Hemostatic forceps toothed , straight	Product Description: Hemostatic forceps, Straight. Toothed. used for haemostasis. length - not less than 198 mm , Material: Martensitic stainless steel (quenched, magnetic steel) composition: 0.20% carbon; 13% chromium. Highly impact resistant. Instructions for use: Hemostatic forceps, used for haemostasis. Hemostatic Forceps can be used to clamp large blood vessels, manipulate heavy tissue, and dissect soft tissue. This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging & Labelling: Unit presentation: forceps single unit, in a plastic bag.

		Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
5	Heaney Uterine Forceps , curved	Product Description: Heaney uterine forceps, curved, used in the uterus. Heaney: jaws curved, double teeth. Length not less than 225 mm, Material: Martensitic stainless steel (quenched, magnetic steel). Material composition (average): 0.16% to 0.25% Carbon, 12 to 14% Chromium. Highly impact resistant. Instructions for use: Used to hold the uterine wall during a hysterectomy or caesarean section. This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging & Labelling: Unit presentation: forceps single unit, in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1:

		General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
6	Heaney Uterine Forceps , curved	Product Description: Heaney uterine forceps, curved, used in the uterus. Heaney: jaws curved, double teeth. Length not less than 240 mm, Material: Martensitic stainless steel (quenched, magnetic steel). Material composition (average): 0.16% to 0.25% Carbon, 12 to 14% Chromium. Highly impact resistant. Instructions for use: Used to hold the uterine wall during a hysterectomy or caesarean section. This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging & Labelling: Unit presentation: forceps single unit, in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements:

		CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
7	Doyen's Cross Action Towel Clips	Product Description: Doyen's Cross Action Towel Clips Length not less than 90 mm, material: Martensitic Stainless Steel(Grade 410). Instructions for use: Used to fix deaping towels. Fixing diathermy cables, suction tubes, etc. May be used to hold ribs while elevating flail segment of chest. This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging & Labelling: Unit presentation: single unit, in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods

		ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
8	MIKULICZ PERITONEAL FORCEPS	Product Description: Mikulicz Peritoneum Forceps Length: not less than 195 mm. Material: Martensitic steel (quenched, magnetic steel) Instructions for use: Mikulicz Peritoneal Forceps are used in gynecological procedures in the pelvic cavity by separating the peritoneal tissue. The forceps feature ring handles with a lock mechanism and curved serrated blades. This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging & Labelling: Unit presentation: Forceps single unit, in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

9	Hemostatic forceps, type: - Mosquito, straight	Product Description: Hemostatic forceps, Type:Mosquito, used for haemostasis. Straight. Haemostatic forceps Spring-type Atraumatic jaws. Flexible arms. Variable settings of the ratchet, lockable. Without teeth. Highly impact resistant. Length: not less than 125mm. Material: Martensitic steel (quenched, magnetic steel). Martensitic steel composition: 0.20% carbon; 13% chromium ; 1% silicon ; 1% manganese. Instructions for use: Hemostatic forceps, Mosquito, used for haemostasis. This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging & Labelling: Unit presentation: single unit, in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

10	Micro Dissectors Microsurgical	Product Description: Micro Dissectors Microsurgical Total Length of instrument: 220 ± 5 mm. working part width: 2.0 ± 0.5 mm Shape: curved up Material: Martensitic stainless steel. Instructions for use: Micro Dissectors are used for tissue separation, which facilitates the dissection of the anatomical elements without traumatizing them. This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser., martensitic stainless steel Packaging & Labelling: Unit presentation: single unit, in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

11	Vaginal retractor (also called vaginal speculum), type: Doyen	Product Description: Vaginal retractor (also called vaginal speculum), Type Doyen. Weight which fits on the shank of the blade. Weight should be soldered/ welded rather than screwed. Lateral edges must be blunt. Blade: hollow shaped. Blade length: not less than 90mm. Blade width: not less than 45mm. Length: not less than 230 mm. Material: Austenitic stainless steel (non-quenched, non-magnetic steel) composition: 18% to 20% chromium; 8 to 10% nickel. Instructions for use: To expose the vaginal cavity. Vaginal retractor (also called vaginal speculum), Type Doyen, for spreading and opening the posterior wall of the vagina to visualize the cervix of the uterus; used to display the cervix in operations of the uterine cavity This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging & Labelling: Unit presentation: single unit, in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

12	Vaginal retractor (also called vaginal speculum), type: Doyen	Product Description: Vaginal retractor (also called vaginal speculum), Type Doyen. Weight which fits on the shank of the blade. Weight should be soldered/ welded rather than screwed. Lateral edges must be blunt. Blade: hollow shaped. Blade length: not less than 90mm. Blade width: not less than 45mm. Length: not less than 230 mm. Material: Austenitic stainless steel (non-quenched, non-magnetic steel) composition: 18% to 20% chromium; 8 to 10% nickel. Instructions for use: To expose the vaginal cavity. Vaginal retractor (also called vaginal speculum), Type Doyen, for spreading and opening the posterior wall of the vagina to visualize the cervix of the uterus; used to display the cervix in operations of the uterine cavity This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging & Labelling: Unit presentation: single unit, in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

13	Vaginal retractor (also called vaginal speculum), type: Doyen	Blade length: not less than 60mm. Blade width: not less than 60mm. Length: not less than 230 mm. Material: Austenitic stainless steel (non-quenched, non-magnetic steel) composition: 18% to 20% chromium; 8 to 10% nickel. Instructions for use: To expose the vaginal cavity. Vaginal retractor (also called vaginal speculum), Type Doyen, for spreading and opening the posterior wall of the vagina to visualize the cervix of the uterus; used to display the cervix in operations of the uterine cavity This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging & Labelling: Unit presentation: single unit, in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
14	Vaginal retractor (also called vaginal speculum), type: Doyen	Product Description: Vaginal retractor (also called vaginal speculum), Type Doyen. Weight which fits on the shank of the blade. Weight should be soldered/ welded rather than screwed. Lateral edges must be blunt. Blade: hollow shaped. working part length Blade length: not less than 90mm. working part Blade width: not less than 60mm.

		Length: not less than 230 mm. Material: Austenitic stainless steel (non-quenched, non-magnetic steel) composition: 18% to 20% chromium; 8 to 10% nickel. Instructions for use: To expose the vaginal cavity. Vaginal retractor (also called vaginal speculum), Type Doyen, for spreading and opening the posterior wall of the vagina to visualize the cervix of the uterus; used to display the cervix in operations of the uterine cavity This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging & Labelling: Unit presentation: single unit, in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
15	Vaginal retractor (also called vaginal speculum), type: Sims	Product Description: Sims, vaginal speculum, double-ended speculum for examining the walls of the vagina and cervix of the uterus Dimensions: not less than 21x85x190mm Material: Austenitic steel (non-quenched, non-magnetic steel). Austenitic steel composition: 16 to 18% chromium; 2 to 3 % molybdenum; 10 to 14% nickel; 1% silicon; 2% manganese (AISI 316/316L) Instructions for use: Speculum for examining the walls of the vagina and cervix of the uterus

		This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging & Labelling: Unit presentation: single unit, in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
16	Vaginal retractor (also called vaginal speculum), type: Sims	Product Description: Sims, vaginal speculum, double-ended speculum for examining the walls of the vagina and cervix of the uterus Dimensions: not less than 24x90x190mm Material: Austenitic steel (non-quenched, non-magnetic steel). Austenitic steel composition: 16 to 18% chromium; 2 to 3 % molybdenum; 10 to 14% nickel; 1% silicon; 2% manganese (AISI 316/316L) Instructions for use: Speculum for examining the walls of the vagina and cervix of the uterus This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging & Labelling: Unit presentation: single unit, in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference.

		Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
17	Vaginal retractor (also called vaginal speculum), type: Sims	Product Description: Sims, vaginal speculum, double-ended speculum for examining the walls of the vagina and cervix of the uterus Dimensions – not less than 28x95x190 mm, Material: Austenitic steel (non-quenched, non-magnetic steel). Austenitic steel composition: 16 to 18% chromium; 2 to 3 % molybdenum; 10 to 14% nickel; 1% silicon; 2% manganese (AISI 316/316L). Instructions for use: Speculum for examining the walls of the vagina and cervix of the uterus This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging & Labelling: Unit presentation: single unit, in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark

		Classification. Class I Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
18	Vaginal retractor (also called vaginal speculum), type: Sims	Product Description: Sims, vaginal speculum, double-ended speculum for examining the walls of the vagina and cervix of the uterus Dimensions – not less than 32x105x195 mm, Material: Austenitic steel (non-quenched, non-magnetic steel). Austenitic steel composition: 16 to 18% chromium; 2 to 3 % molybdenum; 10 to 14% nickel; 1% silicon; 2% manganese (AISI 316/316L). Instructions for use: Speculum for examining the walls of the vagina and cervix of the uterus This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging & Labelling: Unit presentation: single unit, in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes

		EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
19	Vaginal retractor (also called vaginal speculum), type: Sims	Product Description: Sims, vaginal speculum, double-ended speculum for examining the walls of the vagina and cervix of the uterus Dimensions – not less than 32x105x195 36x110x195 mm, Material: Austenitic steel (non-quenched, non-magnetic steel).Austenitic steel composition: 16 to 18% chromium; 2 to 3 % molybdenum; 10 to 14% nickel; 1% silicon; 2% manganese (AISI 316/316L). Instructions for use: Speculum for examining the walls of the vagina and cervix of the uterus This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging & Labelling: Unit presentation: single unit, in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices

		EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
20	Fritsch Abdominal Retractor	Product Description: Fritsch Abdominal Retractor. To retract abdominal organs. Length:not less than 250 mm. Blade:width aprox: 100 mm Material:Austenitic stainless steel (non quenched, non-magnetic steel). Composition 18% to 20% chromium; 8 to 10% nickel. Instructions for use: The Fritsch Retractor is a general purpose device that is used to pull back soft tissue edges to view the underlying tissues, as in abdominal surgeries. This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging & Labelling: Unit presentation: single unit, in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
21	Fritsch Abdominal Retractor	Product Description: Fritsch Abdominal Retractor. To retract abdominal organs. Length:not less than 250 mm. Blade:width aprox: 60 mm

		Material:Austenitic stainless steel (non quenched, non-magnetic steel). Composition 18% to 20% chromium; 8 to 10% nickel. Instructions for use: The Fritsch Retractor is a general purpose device that is used to pull back soft tissue edges to view the underlying tissues, as in abdominal surgeries. This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging & Labelling: Unit presentation: single unit, in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
22	Kocher Vaginal Retractor	Product Description: Kocher Vaginal Retractor. Used to elevate the anterior vaginal wall. Length: not less than 255 mm. Working part Lenght: not less than 85 mm Working part width: not less than 30 mm Material: Austenitic stainless steel (non-quenched, non-magnetic steel). Composition:18% to 20% chromium; 8 to 10% nickel. Instructions for use: Used to elevate the anterior vaginal wall. This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser.

		Packaging & Labelling: Unit presentation: single unit, in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
23	Kocher Vaginal Retractor	Product Description: Kocher Vaginal Retractor. Used to elevate the anterior vaginal wall. Length not less than 250 mm, Working part length not less than 115 mm, working part width not less than 39,6 мм. Material: Austenitic stainless steel (non-quenched, non-magnetic steel) composition: 18% to 20% chromium; 8 to 10% nickel. Instructions for use: Used to elevate the anterior vaginal wall. This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging & Labelling: Unit presentation: single unit, in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable).

		Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
24	Otto Vaginal Retractor	Product Description: Otto Vaginal Retractor. Dimensions at least 30x100x250 мм, Material: Austenitic stainless steel (non-quenched, non-magnetic steel) composition: 18% to 20% chromium; 8 to 10% nickel. Instructions for use: Used in gynecology, surgery and medical examinations to expose the mucous membrane of the vagina, cervix and external uterus. This item must be cleaned, disinfected after each use, and sterilised in a steam sterilise Packaging & Labelling: Unit presentation: single unit, in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC

		CE self-declaration. ISO 13845:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
25	Abdominal Retractors type: Fritsch-Doyen	Product Description: Fritsch-Doyen Abdominal Retractor. Handle Length: aprox 250 mm. Blade:75 mmx45mm Material:Austenitic stainless steel (non-quenched, non-magnetic steel) composition: 18% to 20% chromium; 8 to 10% nickel. Instructions for use: Used to retract the abdominal organs during a cirugy. This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging & Labelling: Unit presentation: single unit, in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods

		ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
26	Doyen Surgical Probes	Product Description: Doyen Surgical Probes. Lenght: not less than 170mm Material: Austenitic steel (non-quenched, non-magnetic steel). Instructions for use: Used in surgery to protect the tissue below the scalpel cut. This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging & Labelling: Unit presentation: single unit, in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
27	Urinary catheters, metal, for female, curved No 14	Product Description: Female metal catheter to be inserted through the urethra. Material : medical stainless steel that can be sterilized. Silver plated finish. Length not less than 150 mm. Curved N°14

		Instructions for use: Instrumet used to be inserted through the urethra. This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging and labelling: One (1) catheter in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process catheters - Test methods for common properties
28	Urinary catheters, metal, for female, curved No 17	Product Description: Female metal catheter to be inserted through the urethra. Material : medical stainless steel that can be sterilized. Silver plated finish. Length not less than 150 mm. Curved N°17 Instructions for use: Instrumet used to be inserted through the urethra. This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging and labelling: One (1) catheter in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable).

		Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process UNE-EN 1618:1997 Catheters other than intravascular catheters - Test methods for common properties
29	Korntsang curved	Product Description: Korntsang curved . Length not less than 250 mm. Material : Martensitic stainless steel (quenched, magnetic steel. composition: 0.20% carbon; 13% chromium. Instructions for use: Designed to provide sterile instruments and dressings for swab insertion and drains. This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging and labelling: One (1) unit in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration.

		ISO 13845:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
30	Korntsang straight	Product Description: Korntsang Straight Material: Martensitic stainless steel (quenched, magnetic steel. composition: 0.20% carbon; 13% chromium. Length not less than 250 mm Instructions for use: Designed to provide sterile instruments and dressings for swab insertion and drains. This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging and labelling: One (1) unit in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices

		EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
31	Volkmann Retractor 4 Prong Sharp	Product Description: Volkmann Retractor 4 Prong Sharp. The Volkmann Retractor has sharp teeth to retract the skin / subcutaneous tissue. Length: not less than 200mm. 4 Prong Sharp. Material: Martensitic steel (quenched, magnetic steel) Instructions for use: The Volkmann Retractor has sharp teeth to retract skin / subcutaneous tissue and a hard facia. It is also used in small bones and joint procedures. This item must be cleaned, disinfected after each use, and sterilised in a steam sterilizer Packaging and labelling: One (1) unit in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
32	Volkmann Retractor 4 Prong Blunt	Product Description: Volkmann Retractor 4 Prong Blunt. Material: Martensitic steel (quenched, magnetic steel). Length not less than 220 mm, Instructions for use:

		The Volkmann retractor aims to retract structures in order to achieve a better exposure of the surgical field. This item must be cleaned, disinfected after each use, and sterilised in a steam sterilizer Packaging and labelling: One (1) unit in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
33	Curette Uterine Sharp	Product Description: Curette Uterine Sharp Uterine curette for scrapping and removal of retained products of conception from inside the uterus. Shank type: Rigid. Blade shape: Oval, fenestrated. Blade edge type: Sharp. Length: shaft approx. 300mm. Width: spoon approx. 13mm. Material: Martensitic steel (quenched, magnetic steel). Instructions for use: A uterine curette is an instrument used to scrape and remove material from the uterus. This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging and labelling: One (1) curette in a plastic bag.

		Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements CE mark conforming to Medical Device Directive 93/42/EEC ISO 13485:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
34	Curette Uterine Blunt	Product Description:Curette Uterine Blunt Uterine curette for scrapping and removal of retained products of conception from inside the uterus Shank type: Rigid. Blade shape: Oval, fenestrated. Blade edge type: Blunt. Length: shaft approx. 310mm. Width: spoon Diameter approx. 11mm. Material: Martensitic steel (quenched, magnetic steel). Instructions for use: A uterine curette is an instrument used to scrape and remove material from the uterus. This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging and labelling: One (1) curette in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference.

		Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements CE mark conforming to Medical Device Directive 93/42/EEC ISO 13485:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
35	Curette Uterine Blunt	Product Description: Curette Uterine Blunt Uterine curette for scrapping and removal of retained products of conception from inside the uterus Shank type: Rigid. Blade shape: Oval, fenestrated. Blade edge type: Blunt. Length: shaft approx. 310mm. Width: spoon Diameter approx. 18mm. Material: Martensitic steel (quenched, magnetic steel). Instructions for use: A uterine curette is an instrument used to scrape and remove material from the uterus. This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging and labelling: One (1) curette in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable).

		Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements CE mark conforming to Medical Device Directive 93/42/EEC ISO 13485:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
36	Curette Uterine Blunt	Product Description: Curette Uterine Blunt Uterine curette for scrapping and removal of retained products of conception from inside the uterus Shank type: Rigid. Blade shape: Oval, fenestrated. Blade edge type: Blunt. Length: shaft approx. 310mm. Width: spoon Diameter approx. 17mm. Material: Martensitic steel (quenched, magnetic steel). Instructions for use: A uterine curette is an instrument used to scrape and remove material from the uterus. This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging and labelling: One (1) curette in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1:

		General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements CE mark conforming to Medical Device Directive 93/42/EEC ISO 13485:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
37	RETRACTOR/SPATULA, REVERDIN	Product Description Retractor/spatula, abdominal, Reverdin Length not less than 212 mm, Material: Austenitic stainless steel (non-quenched, non-magnetic steel) composition: From 17% to19 % chromium and From 8% to 10% nickel. Instructions for use: Used to protect intra-abdominal structures during abdominal wall closure. This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging and labelling: One (1) unit in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements CE mark conforming to Medical Device Directive 93/42/EEC ISO 13485:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes

		EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
38	UMBILICAL CORD SCISSORS CURVED SIDEWARDS	Product Description: UMBILICAL CORD SCISSORS, Profile: CURVED SIDEWARDS. Handle Type: Ring Handle Length not less 150 mm. Material: Martensitic stainless steel (quenched, magnetic steel) composition: 0.40 % carbon; 14% chromium Instructions for use: Umbilical cord scissors are used in labor (obstetric) procedures to cut the umbilical cord after the cord is appropriately clamped. This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging and labelling: One (1) unit in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements CE mark conforming to Medical Device Directive 93/42/EEC ISO 13485:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices

		EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
39	Blot's Perforator	Product Description: Blot's Perforator. Length not less 345 mm. Material: Carbon Steel and electroplated aluminum. Instructions for use: Used for perforation of the fetal head during fetal-destructive operations and the formation of holes in the uterine wall during gynecological operations.This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging and labelling: One (1) unit in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements CE mark conforming to Medical Device Directive 93/42/EEC ISO 13485:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
40	Brunner Abdominal Retractor	Product Description: Brunner Abdominal Retractor.. Length: 255mm(±5).Blade size: 100x25 mm (±5) Material: Austenitic steel. Material composition: 16 -18% chromium; 2-3% molybdenum; 8 -10% nickel ; 1% silicon ; 2% manganese Instructions for use: The Brunner Retractor is used to retract soft tissues and enhance the surgical field in pelvic surgeries and procedures. This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser.

		Packaging and labelling: One (1) unit in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements CE mark conforming to Medical Device Directive 93/42/EEC ISO 13485:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
41	Forceps, intestinal, Duval (tweezer)	Product Description: Forceps, Duval, for gripping and holding bulky ,soft and delicate tissues (lung and intestines). Material: Martensitic stainless steel (quenched, magnetic steel) Non-traumatic parallel serrations. Flexible arms. Soft ratchet, lockable. Pronounced but non traumatic ridges of the grippers. Ridged grippers with aperture (triangular). Highly impact resistant Length: not less 125 mm. Jaw: approximately 27mm. Instructions for use: Used to grip and hold bulky, soft and delicate tissues (lung and intestines). This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging and labelling: One (1) unit in a plastic bag. Labelling on the primary packaging:

		Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements CE mark conforming to Medical Device Directive 93/42/EEC ISO 13485:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
42	Russian Tissue Forceps	Product Description: Russian Tissue Forceps. The forceps are straight with a circular cup-shaped serrated tip. dimensions - at least 150x5.5 mm, Material: Martensitic steel (quenched, magnetic steel). Highly impact resistant Instructions for use: Russian Forceps are used for grasping heavy or thick tissue. The forceps are straight with a circular cup-shaped serrated tip, The forceps are also used in wounds closure procedures.This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging and labelling: One (1) unit in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark

		Classification. Class I Regulation & conformity requirements CE mark conforming to Medical Device Directive 93/42/EEC ISO 13485:2016 certified Safety & product Standards: Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
43	Forceps,tissue,standard,dissecting,1x2 teeth	Product Description: Dissecting forceps, springy. Fine serrated jaw Dissecting forceps used in deep surgery for gripping and dissecting tissues as well as coagulation of vessels. Forceps with teeth are used for dissecting thick tissues. Straight. With 1 x 2 teeth. Flexible arms. Good adjustment of the teeth. Good jaw grips. Material: Martensitic steel (quenched, magnetic steel). Highly impact resistant. Length: not less 150 mm Instructions for use: Used for gripping, dissecting tissue and coagulation of vessels. Used in surgery and nursing. Forceps with teeth are used for dissecting thick tissues. This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging and labelling: One (1) forceps in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements CE mark conforming to Medical Device Directive 93/42/EEC

		ISO 13485:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
44	Forceps,tissue,standard,dissecting,1x2 teeth	Product Description: Dissecting forceps, springy.Fine serrated jaw Dissecting forceps used in deep surgery for gripping and dissecting tissues as well as coagulation of vessels. Forceps with teeth are used for dissecting thick tissues. Straight. With 1 x 2 teeth. Flexible arms. Good adjustment of the teeth. Good jaw grips. Material: Martensitic steel (quenched, magnetic steel). Highly impact resistant. Length: not less 250 mm Instructions for use: Used for gripping, dissecting tissue and coagulation of vessels. Used in surgery and nursing. Forceps with teeth are used for dissecting thick tissues. This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging and labelling: One (1) forceps in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements CE mark conforming to Medical Device Directive 93/42/EEC ISO 13485:2016 certified Safety & product Standards:

		ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
45	Retractor/spatula, abdominal, Reverdin	Product Description Retractor/spatula, abdominal, Reverdin Length not less than 285 mm, width of the working part not less than 70 mm, Material: Austenitic stainless steel (non-quenched, non-magnetic steel) composition: From 17% to19 % chromium and From 8% to 10% nickel. Instructions for use: Used to protect intra-abdominal structures during abdominal wall closure. This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging and labelling: One (1) forceps in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements CE mark conforming to Medical Device Directive 93/42/EEC ISO 13485:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices

		EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
46	Retractor, abdominal, Frisch	Product Description: Fritsch Abdominal Retractor. Abdominal wall retractor. Handle Length: aprox 250 mm. Blade:75 mmx45mm Material:Austenitic stainless steel (non-quenched, non-magnetic steel) composition: 18% to 20% chromium; 8 to 10% nickel. Instructions for use: Used to retract the abdominal wall to provide exposure during a laparotomy. This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging and labelling: One (1) unit in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements CE mark conforming to Medical Device Directive 93/42/EEC ISO 13485:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
47	Corkscrew for grasping fibromyoma	Product Description: Corkscrew for grasping fibromyoma Length not less than 175 mm, Material: medical stainless steel. Instructions for use: Corkscrew for grasping fibromyoma. This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser.

		Packaging and labelling: One (1) forceps in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements CE mark conforming to Medical Device Directive 93/42/EEC ISO 13485:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
48	Forceps uterine 2x2 straight : Museux	Product Description: Forceps uterine 2x2 straight : Museux Material: Martensitic stainless steel (quenched, magnetic steel) Martensitic stainless steel composition: 0.20% carbon; 13% chromium.1% silicon; 1 % maganese. Gripping forceps with teeth: 2 x 2 teeth. Straight Precise adjustment of the teeth. Highly impact resistant. Length: not less than 200mm. Jaws: 80-100mm. Instructions for use: Uterine traction forceps. Uterine forceps are intended to scrape, cut, grasp, hold, remove, or manipulate tissue or structures.This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging and labelling: One (1) forceps in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable).

		Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements CE mark conforming to Medical Device Directive 93/42/EEC ISO 13485:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
49	Forceps uterine 2x2 straight type :Museux	Product Description: Forceps uterine 2x2 straight : Museux Material: Martensitic stainless steel (quenched, magnetic steel) Martensitic stainless steel composition: 0.20% carbon; 13% chromium.1% silicon; 1 % maganese. Gripping forceps with teeth: 2 x 2 teeth. Straight Precise adjustment of the teeth. Highly impact resistant. Length: not less than 240mm. Jaws: 80-100mm. Instructions for use: Uterine traction forceps. Uterine forceps are intended to scrape, cut, grasp, hold, remove, or manipulate tissue or structures.This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser Packaging and labelling: One (1) unit in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements CE mark conforming to Medical Device Directive 93/42/EEC

		ISO 13485:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
50	Uterine Polypus Forceps With Fenestrated Serrated Jaws	Product Description: Uterine Polypus Forceps With Fenestrated Serrated Jaws. Length:not less than 225 mm, loop width: aprox 13 mm, Material: Martensitic stainless steel (quenched, magnetic steel) composition: 0.20% carbon; 13% chromium. Instructions for use: A hand-held surgical instrument used to atraumatically grasp and hold various anatomical tissues during the surgical treatment, mitigation, prevention, and/or diagnosis of obstetrical/ gynecological disease or conditions. This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser. Packaging and labelling: One (1) forceps in a plastic bag. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer.. Manufacturer's product reference. Lot number prefixed by the word "LOT"(or equivalent harmonised symbol, if applicable). Symbols used according ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements and UNE-EN 980:2008 Symbols for use in the labelling of medical devices CE mark Classification. Class I Regulation & conformity requirements CE mark conforming to Medical Device Directive 93/42/EEC ISO 13485:2016 certified Safety & product Standards: ISO 13485: 2016 Quality management systems -- Requirements for regulatory purposes EN ISO 14971:2012 Medical Devices- Application of risk management to medical devices ISO 7153-1:2016 Surgical instruments - Materials - Part 1: Metals ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods

		ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion, and thermal exposure. ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices EN ISO 10993-1:2009:Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

LOT 4 Glucometer

NAME, CATEGORY AND CODING		Required Specification
1	Generic name	Glucometer, Blood Glucose Meter, Glucose monitor, Blood Sugar Meter
2	Specific type or variation (optional)	Express method or fast analysis, using test strips
PURPOSE OF USE		
3	Clinical or other purpose	Fast analysis of blood glucose levels, to manage of both hypoglycemic and hyperglycemic disorders with the goal of adjusting the blood glucose to a near-normal range of the patient.
4	Level of use (if relevant)	Health center, district hospital, provincial hospital, specialized hospital
5	Clinical department/ward(if relevant)	Point of care as intensive care and reanimation unit
TECHNICAL CHARACTERISTICS		
6	Detailed requirements	Handheld device with an LCD display, Slot to insert a test strip containing a drop of blood which is tested for glucose, Measurement Method: Photometric; Measurement range: Approximately 0.56-33.3 mmol / L (10-600mg/dl); System operating temperature: wide operating temperature Automatic inclusion when introducing a test strip; Blood drop volume: 0.5-2 µl; Measurement time: Approximately 5 seconds (less than 10 sec.); Alarms and memory functions, Wireless or USB port to transfer data to a computer, Battery Life:more than 1000 measurements
7	Displayed parameters	Display: Liquid Crystal Display (LCD)
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
8	Accessories (if relevant)	50 pieces of test strips and pen piercer with 50 pieces of lancets. Test strips and battery should be available locally in Uzbekistan.
9	Packaging & Labelling:	One (1) Glucometer with accessories and consumables Symbols used according ISO 15223 Manufacturer's product code or reference number. Manufacturer identification. Address of the manufacturing site. How the device should be used, maintained and stored. Any residual device risks, warnings, limitations or contraindications.
WARRANTY AND MAINTENANCE		

10	Warranty	At least 12 months from the date of commissioning.
11	Type of service contract	The equipment must be new, not used, produced not earlier than 2019
DOCUMENTATION		
12	Documentation requirements	Operation Manual and Maintenance Instruction and Labels in Russian and English
SAFETY AND STANDARDS		
13	Risk Classification	In vitro diagnostic (IVDR 2017/746)
14	Regulatory Approval / Certification	CE mark or FDA 510k approved or equivalent. Declaration of Conformity according to ISO 17050. ISO 13485
15	International standards	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) EN ISO 13485:2016/AC:2018 EN ISO 14971:2012 Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01) EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03) EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices EN ISO 23640:2015 In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011) EN ISO 15197:2015 In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus (ISO 15197:2013) EN ISO 17511:2003 In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials (ISO 17511:2003) EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009) EN ISO 18113-3:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use (ISO 18113-3:2009) IEC 61010-2-101:2002 Safety requirements for electrical equipment for measurement, control, and laboratory use -- Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment IEC 61326-2-6:2005 Electrical equipment for measurement, control and laboratory use - EMC requirements -- Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment IEC 62304:2006 Medical device software - Software life-cycle processes IEC 62366:2007 Medical devices - Application of usability engineering to medical devices **Environmental Requirements (are desirable):** ISO 14001: Environmental management systems ISO 50001: Energy management systems

LOT 5 Medical Console and Compressor

1. Wall mounted medical console

NAME, CATEGORY AND CODING		Required Specification
1.	Generic name	Wall mounted medical console, Medical supply unit.
PURPOSE OF USE		
1.	Clinical or other purpose	Medical supply unit provides a permanently mounted location supplying facilities such as: electricity, medical gases (oxygen, compressed air), vacuum, communications (as assistance from nursing and network), illumination options and support for other medicals devices.
TECHNICAL CHARACTERISTICS		
2.	Detailed requirements	Wall mounted medical supply unit, Length: approximately 2 m long; Material: aluminum. Color-coded for easy gas identification Supplied with: Gas sockets: 2 pcs for oxygen + 2 pcs for medical air + 1 pcs for vaccum (DIN or according Uzbekistan´s standards); Flowmeter regulator with Humidifier: 2 pcs; Suction regulator with suction Trap: 1 pcs; Electrical outlets with grounding: 6 pcs. according the Uzbekistan´s plug. Crossbar for fastening attachments as syringe and infusion pumps, baskets, etc.; Infusion rack with solution baskets; Shelf for monitor; Night-time lighting; Communication system.
UTILITY REQUIREMENTS		
3.	Electrical supply	220 V , 50 Hz.
4.	Environmental requirements	Possibility of continuous storage at ambient temperature from -20°C to +60 °C and relative humidity from 10% to 95%. It should be able to work continuously at an ambient temperature of 5 °C to 40 °C and a relative humidity of 15% to 95%.
TRAINING, INSTALLATION AND UTILISATION		
5.	Commissioning requirements	To confirm the completion of the installation, the supplier must perform the installation, safety and operation check before transferring it to the local clinic staff.
6.	Training of user/s	User training for operation and basic maintenance.
WARRANTY AND MAINTENANCE		
7.	Warranty	At least 12 months from the date of commissioning.
DOCUMENTATION		
8.	Documentation requirements	Operational and Service Manual in Russian and English
SAFETY AND STANDARDS		
9.	Risk Classification	Medical devices Class IIb (MDR 2017/745)
10.	Regulatory Approval / Certification	CE mark or FDA 510k approved or equivalent. Declaration of Conformity according to ISO 17050. ISO 13485
11.	International standards	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) EN ISO 13485:2016/AC:2018

		EN ISO 14971:2012 Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01) EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03) EN 1041:2008 Information supplied by the manufacturer of medical devices EN ISO 11197 Medical supply units EN ISO 7396-1 Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum IEC 60601-1:2005+AMD1:2012 CSV Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests IEC 62366:2007 Medical devices - Application of usability engineering to medical devices ISO 9170-1:2017 Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum **Environmental Requirements (are desirable):** ISO 14001: Environmental management systems ISO 50001: Energy management systems

1. Medical Compressor

NAME, CATEGORY AND CODING		Required Specification
1.	Generic name	Medical air compressor
PURPOSE OF USE		
2.	Clinical or other purpose	Fresh compressed air supply equipment to medical devices
TECHNICAL CHARACTERISTICS		
3.	Detailed requirements	Oil free air compressor; Dry air system; Airflow: 0.3 m3/min (approximately 300L/min) Working pressure: approximately 6.0 bar. Number of compression stages: 1 Wire type: screw Built-in air receiver (tank): 50 L Steel air tank material (approved for storage medical air); Cooling type: Air Air Engine power: 3,7 kW (approximately 5HP); Safety and drain valve included.
UTILITY REQUIREMENTS		
4.	Electrical supply	220 V , 50 Hz.
5.	Environmental requirements	Continuous storage at ambient temperature from -20°C to +60 °C and relative humidity from 10% to 95%. Able to operate continuously at an ambient temperature of 5 °C to 40 °C and a relative humidity of 15% to 95%.

TRAINING, INSTALLATION AND UTILISATION		
6.	Commissioning requirements	To confirm the completion of the installation, the supplier must complete the installation, safety and operation check before handing it over to the local clinic staff.
7.	Training of user/s	User training for operation and basic maintenance.
WARRANTY AND MAINTENANCE		
8.	Warranty	At least 12 months from the date of commissioning.
DOCUMENTATION		
9.	Documentation requirements	Operational and Service Manual in Russian and English
SAFETY AND STANDARDS		
10.	Regulatory Approval / Certification	CE mark or FDA approved or equivalent. Declaration of Conformity according to ISO 17050. ISO9001 and ISO 13485
11.	International standards	ISO 9001:2015 Quality management system EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) EN ISO 13485:2016/AC:2018 EN ISO 14971:2012 Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01) EN 1041:2008 Information supplied by the manufacturer of medical devices EN 1012-1 Compressors and vacuum pumps – Safety requirements ISO 2151, Acoustics — Noise test code for compressors and vacuum pumps — Engineering method (Grade 2) ISO 8573-1, Compressed air — Part 1: Contaminants and purity classes ISO 8573-2, Compressed air — Contaminant measurement — Part 2: Oil aerosol content ISO 8573-3, Compressed air — Part 3: Test methods for measurement of humidity ISO 8573-4, Compressed air — Contaminant measurement — Part 4: Particle content **Environmental Requirements (are desirable):** ISO 14001: Environmental management systems ISO 50001: Energy management systems

2.2 Schedule of Requirements

The Bidder shall also furnish a list giving full particulars, including available sources and current prices of spare parts, special tools, etc., necessary for the proper and continuing functioning of the goods during *10 years* following commencement of the use of the goods by UNFPA.

LOT 1 Medical Equipment

1. List of Goods and Delivery Schedule

Line Item	Description of Goods	Quantity	Unit of measure	Delivery Schedule from date of Contract
1	Operating table with accessories	3	EA.	ASAP
2	Capnograph	3	EA.	ASAP
3	Ultrasound scanner with Doppler	3	EA.	ASAP
4	Electrocoagulation Equipment	3	EA.	ASAP

5	Obstetric table	12	EA.	ASAP

LOT 2 Medical Furniture

2. List of Goods and Delivery Schedule

Line Item	Description of Goods	Quantity	Unit of measure	Delivery Schedule from date of Contract
1	Medical Examination Couch	9	EA.	ASAP
2	Stool (rotating)	9	EA.	ASAP
3	Manipulation table	9	EA.	ASAP
4	Instrument Cabinet	9	EA.	ASAP
5	Patient carrying Trolley	9	EA.	ASAP
6	Anesthesiologist table	9	EA.	ASAP
7	Mobile surgical instrument table	9	EA.	ASAP
8	IV infusion stand	9	EA.	ASAP

LOT 3 Surgical Instruments

3. List of Goods and Delivery Schedule

Line Item	Description of Goods	Quantity	Unit of measure	Delivery Schedule from date of Contract
1	Hemostatic forceps 1x2 teeth , straight	30	EA.	ASAP
2	Hemostatic forceps toothed , curved	30	EA.	ASAP
3	Hemostatic forceps toothed , straight	30	EA.	ASAP
4	Hemostatic forceps toothed , straight	30	EA.	ASAP
5	Heaney Uterine Forceps , curved	12	EA.	ASAP
6	Heaney Uterine Forceps , curved	12	EA.	ASAP
7	Doyen's Cross Action Towel Clips	30	EA.	ASAP
8	MIKULICZ PERITONEAL FORCEPS	30	EA.	ASAP
9	Hemostatic forceps, type: - Mosquito, straight	30	EA.	ASAP
10	Micro Dissectors Microsurgical	3	EA.	ASAP
11	Vaginal retractor (also called vaginal speculum), type: Doyen	3	EA.	ASAP
12	Vaginal retractor (also called vaginal speculum), type: Doyen	3	EA.	ASAP
13	Vaginal retractor (also called vaginal speculum), type: Doyen	3	EA.	ASAP
14	Vaginal retractor (also called vaginal speculum), type: Doyen	3	EA.	ASAP
15	Vaginal retractor (also called vaginal speculum), type: Sims	3	EA.	ASAP
16	Vaginal retractor (also called vaginal speculum), type: Sims	6	EA.	ASAP
17	Vaginal retractor (also called vaginal speculum), type: Sims	6	EA.	ASAP
18	Vaginal retractor (also called vaginal speculum), type: Sims	6	EA.	ASAP

19	Vaginal retractor (also called vaginal speculum), type: Sims	3	EA.	ASAP
20	Fritsch Abdominal Retractor	3	EA.	ASAP
21	Fritsch Abdominal Retractor	3	EA.	ASAP
22	Kocher Vaginal Retractor	6	EA.	ASAP
23	Kocher Vaginal Retractor	6	EA.	ASAP
24	Otto Vaginal Retractor	9	EA.	ASAP
25	Abdominal Retractors type: Fritsch-Doyen	6	EA.	ASAP
26	Doyen Surgical Probes	3	EA.	ASAP
27	Urinary catheters , metal , for female, curved No 14	6	EA.	ASAP
28	Urinary catheters , metal , for female, curved No 17	6	EA.	ASAP
29	Korntsang curved	15	EA.	ASAP
30	Korntsang straight	30	EA.	ASAP
31	Volkmann Retractor 4 Prong Sharp	6	EA.	ASAP
32	Volkmann Retractor 4 Prong Blunt	6	EA.	ASAP
33	Curette Uterine Sharp	6	EA.	ASAP
34	Curette Uterine Blunt	6	EA.	ASAP
35	Curette Uterine Blunt	6	EA.	ASAP
36	Curette Uterine Blunt	6	EA.	ASAP
37	RETRACTOR/SPATULA, REVERDIN	6	EA.	ASAP
38	UMBILICAL CORD SCISSORS CURVED SIDEWARDS	6	EA.	ASAP
39	Blot's Perforator	3	EA.	ASAP
40	Brunner Abdominal Retractor	3	EA.	ASAP
41	Forceps, intestinal, Duval (tweezer)	3	EA.	ASAP
42	Russian Tissue Forceps	15	EA.	ASAP
43	Forceps,tissue,standard,dissecting,1x2 teeth	6	EA.	ASAP
44	Forceps,tissue,standard,dissecting,1x2 teeth	6	EA.	ASAP
45	Retractor/spatula, abdominal, Reverdin	3	EA.	ASAP
46	Retractor, abdominal, Frisch	3	EA.	ASAP
47	Corkscrew for grasping fibromyoma	3	EA.	ASAP
48	Forceps uterine 2x2 straight : Museux	18	EA.	ASAP
49	Forceps uterine 2x2 straight type :Museux	18	EA.	ASAP
50	Uterine Polypus Forceps With Fenestrated Serrated Jaws	30	EA.	ASAP

LOT 4 Glucometer

4. List of Goods and Delivery Schedule

Line Item	Description of Goods	Quantity	Unit of measure	Delivery Schedule from date of Contract
1	Glucometer	6	EA.	ASAP

LOT 5 Medical Compressor and Medical Console

5. List of Goods and Delivery Schedule

Line Item	Description of Goods	Quantity	Unit of measure	Delivery Schedule from date of Contract
1	Medical Compressor	3	EA.	ASAP
2	Medical Console	14	EA.	ASAP

6. Consignee Address and Consignee-wise Quantity Distribution

Line Item	Consignee Address	Contact person *[May be different from consignee person]*	Quantity	Unit of measure
1	*UNFPA CO in Uzbekistan, Yu Yu, 14, Mahmud Tarobiy Str., Tashkent, Uzbekistan Telephone: (998-71) 281-58-81/83*	*Umid Ermanov, Adminstrative and Finance Associate, Telephone: (998-71) 281-58-81/83 ermanov@unfpa.org*		*EA*

7. List of Related Services and Completion Schedule

No.	Description of Service	Quantity	Physical Unit	Place where Services shall be performed	Final Completion Date(s) of Services
1.	*Operating table Installation and training of users*	*3*	*3*	*Nukus city and Kungrad district of the Republic of Karakalpakstan*	*ASAP*
2.	*Capnograph Installation and Training of Users*	3	3	*Nukus city ,Kungrad and Beruniy districts of the Republic of Karakalpakstan*	*ASAP*
3	*Ultrasound Scanner with Doppler Installation and Training of Users*	3	3	*Nukus city ,Kungrad and Beruniy districts of the Republic of Karakalpakstan*	*ASAP*

4	*Electrocoagulation Equipment Installation and Training of Users*	3	3	*Nukus city ,Kungrad and Beruniy districts of the Republic of Karakalpakstan*	*ASAP*
5	*Obstetric table installation and training of users*	12	12	*Nukus city ,Kungrad and Beruniy districts of the Republic of Karakalpakstan*	*ASAP*
6	*Medical console installation and training of users*	3	3	*Nukus city ,Kungrad and Beruniy districts of the Republic of Karakalpakstan*	*ASAP*
7	*Medical compressor installation and training of users*	14	3	*Nukus city ,Kungrad and Beruniy districts of the Republic of Karakalpakstan*	*ASAP*