United Nations Population Fund
Address: 14, Mahmud Tarobiy Str., Tashkent, Uzbekistan
Fax: (998-71) 120-68-97
Telephone: (998-71) 281-58-81/83
Email: uzbekistan.office@unfpa.org Website: www.uzbekistan.unfpa.org

[14, July, 2020]

INVITATION TO BID
ITB No. UNFPA/UZB/20/001

MANUFACTURE AND/OR SUPPLY OF MEDICAL EQUIPMENT, INSTRUMENTS AND FURNITURE
INTRODUCTORY LETTER

Dear Sir/Madam,

1. The United Nations Population Fund (UNFPA), an international development agency, invites sealed bids for the supply of :
   LOT 1 Medical Equipment, installation, training of users and aftersales services
   LOT 2 Medical furniture
   LOT 3 Obstetric and Surgical Instruments
   LOT 4 Glucometer
   LOT 5 Medical compressor and Medical console, installation and aftersales services
   for its programme in Nukus, Uzbekistan.

2. Bidding shall be conducted through ONE envelope. The technical bid containing the technical specifications and the financial bid containing price information shall be submitted together.

3. The Bidder shall *not be* required to quote for all items. However, Bidders are encouraged to quote for all items within the given LOT .
4. To enable you to submit a bid, please read the following attached documents carefully:

Section I:	Instructions to Bidders
Section II:	Technical Specifications and Schedule of Requirements
Section III:	UNFPA General Conditions of Contract
Section IV:	UNFPA Special Conditions for Contracts
Section V:	Bidding Forms

5. The bid shall reach UNFPA's reception or the email inbox of rfq.uzb@unfpa.org no later than *[6 August, 2020]*, at 18:00 Uzbekistan time [1].

6. The bid shall be opened on *[7 August, 2020]*, at *10 am* at *14, Mahmud Tarobiy Str., Tashkent, Uzbekistan.* Bidders or their authorized representatives may attend the bid opening. Kindly confirm by e-mail by *[31 July, 2020]*, whether your company shall be represented at the bid opening.

7. Bids received after the stipulated date and time shall not be accepted under any circumstances. Bids delivered through courier and posted later than the due date shall not be registered and

[1] *Reference: www.timeanddate.com/worldclock*

shall be returned unopened or shall be shredded. Bids submitted to any other email address than rfq.uzb@unfpa.org shall be rejected.

8. Bidders shall acknowledge receipt of this Invitation to Bid according to the Bid Confirmation Form, Section V, 1 of this solicitation document by email to *Mr. Umid Ermanov, Admin Finance Associate at ermanov@unfpa.org* no later than *[31 July,2020]* and to indicate whether or not a bid shall be submitted. The acknowledgement shall provide company name, telephone number, fax number and the name of a contact person. If you are declining to bid, please confirm this via e-mail to UNFPA and please state the reasons for UNFPA to improve its effectiveness in future invitations.

9. Any questions relating to the attached documents shall be addressed in writing to the following UNFPA personnel no later than *[27 July,2020]* at *18:00, Uzbekistan time.*

   - *[Umid Ermanov, Administrative and Finance Associate]* email: *[ermanov@unfpa.org]* for questions relating to the bidding exercise.

   Do not submit your bid to this contact, or your bid will be disqualified.

10. This letter is not to be construed in any way as an offer to contract with your firm.

11. UNFPA strongly encourages all Bidders to register on the United Nations Global Marketplace (http://www.ungm.org). The UNGM is the procurement portal of the United Nations system. By registering on UNGM, vendors become part of the database that UN buyers use when searching for suppliers. Vendors can also access all UN tenders online and, by subscribing to the Bid Tender Service, vendors can be automatically notified via e-mail of all UN business opportunities that match the products and services for which they have registered. Instructions on how to subscribe to the Tender Alert Service can be found in the UNGM Interactive Guide for Suppliers http://www.ungm.org/Publications/UserManuals/Suppliers/UserManual_Supplier.pdf .

Yours sincerely,

DocuSigned by:
Yu Yu
29187476D7FC455...

Yu Yu
UNFPA Representative in Uzbekistan
[UNFPA Uzbekistan Country Office]

UNITED NATIONS POPULATION FUND

INVITATION TO BID

ITB NO.: UNFPA/UZB/20/001 *(Uzbekistan/20/001)*

Bid document for the manufacture and/or supply of medical equipment, instruments and furniture

14 July 2020

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SECTION I: Instructions to Bidders

A. Introduction

1. Scope

1.1. The goods to be procured *are:*
LOT 1 Medical Equipment, installation, training of users and aftersales services
LOT 2 Medical furniture
LOT 3 Obstetric and Surgical Instruments
LOT 4 Glucometer
LOT 5 Medical compressor and Medical console, installation and aftersales services
for UNFPA's *Programme* located in *Uzbekistan*

2. Eligible Bidders

2.1. All Bidders found to have a conflict of interest shall be disqualified. Bidders may be considered to have a conflict of interest if they are or have been associated in the past, with a firm or any of its affiliates that have been engaged by UNFPA to provide consulting services under these bidding documents.

2.2. Bidders shall not be eligible to submit a bid if at the time of bid submission:
a. The Bidder is listed as suspended on United Nations Global Marketplace (http://www.ungm.org) as a result of having committed fraudulent activities,
b. The Bidder's name is mentioned in the UN 1267 list issued by the Security Council resolution 1267 that establishes a sanctions regime to cover individuals and entities associated with Al-Qaida and/or the Taliban;
c. The Bidder is debarred by the World Bank Group.

Fraud and Corruption

3.1 UNFPA's policy regarding fraud and corruption is available at http://www.unfpa.org/about-procurement#FraudCorruption and applies fully to this Invitation to Bid. The submission of any offer implies that the Bidder is aware of this policy.

B. Solicitation Documents

4 UNFPA Solicitation document

4.1. Bidders are expected to examine all instructions, forms, specifications, terms and conditions contained within this UNFPA solicitation document. Failure to comply with these documents shall be at the Bidder's risk and may affect the evaluation of the bids, or may result in the rejection of the bid.

4.2. Bidders are cautioned to read the specifications carefully (see Section II Technical Specifications and Schedule of Requirements), as there may be special requirements. The technical specifications presented herein are not to be construed as defining a particular manufacturer's product. Bidders are encouraged to advise UNFPA if they disagree.

4.3. The specifications are the minimum requirements for the products and related services. Products and services offered must meet or exceed all requirements herein. The products shall conform in strength, quality and workmanship to the accepted standards of the relevant industry. Modifications of or additions to basic standard products of less size or capability to meet these requirements will not be acceptable.

5 Clarifications of solicitation document

5.1 A prospective Bidder requiring any clarification on the bid solicitation documents may notify UNFPA in writing within *two weeks* from the date of issue of the bid. UNFPA shall respond in writing to any request for clarification received and circulate its response (including an explanation of the query but without identifying the source of enquiry) to all prospective Bidders who have received the bid solicitation documents. A copy of UNFPA's answer shall also be posted on the UN Global Marketplace, http://www.ungm.org/

6 Amendments to UNFPA bid solicitation document

6.1. At any time prior to the deadline for submission of bids, UNFPA may for any reason, whether at its own initiative or in response to a clarification requested by a prospective Bidder, modify the bidding documents by amendment.

6.2. All prospective Bidders that have received the bidding documents shall be notified in writing of all the amendments to the bidding documents. In order to give prospective Bidders reasonable time to take the amendments into account in preparing their bids UNFPA may, at its discretion, extend the deadline for the submission of bids.

C. Preparation of Bids

7 Documents to be submitted with the bid

7.1. **Documents Establishing the Eligibility of the Bidder**

To establish their eligibility, Bidders shall:

a. Complete the Bid Submission Form, Section V, 2.
b. Complete Bidders Identification Form, Section V, 3.

7.2. **Documents Establishing the Qualifications of the Bidder**

To establish its qualifications, the Bidder shall submit to UNFPA's satisfaction the following documents:

a. Evidence that the Bidder is established as a company and legally incorporated in the country where it resides; e.g. through provision of certification of incorporation or other documentary evidence (this is not required for companies already registered in national, regional or international Stock Exchanges);
b. Post qualification documentation outlined in Instructions to Bidders, Sub-Clause 27

Failure to furnish all the information required for submission shall be at the Bidder's risk as it may then be determined that the bid does not substantially respond to the UNFPA bid document in every respect. This may result in a rejection of the bid.

7.3. **Documents Establishing the Eligibility and Conformity of the Goods and Related Services**

Bidders shall submit:

a. Documentary evidence that the goods conform to the Technical Specifications and standards specified in Section II Technical Specifications and Schedule of Requirements.

b. Completed Product Item Overview Form, Section V, 4.
c. Product catalogues containing pictures of the product(s)
d. Manufacturer's technical product specifications or datasheets
e. Results of any testing carried out on the products
f. Copies of current certificates such as GMP/quality, FSC/CPP, manufacturer's ISO certificate for the product, manufacturer's CE certificate, USA 510k, Japan QS standard, etc., as stated in the Technical Specifications and Schedule of Requirements Section II
g. 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. Bidders must complete and submit with their bid the Excel table containing the individual item details, as per Form in Section V.4. Bidding Forms.

8 Bid Currency and Prices

8.1. All prices shall be quoted in any convertible currency to US Dollars (USD).

8.2. Bidders are requested to quote the following based on INCOTERMS 2010 (The terms FCA, CPT and other similar terms shall be governed by the rules prescribed in the INCOTERMS 2010, published by the International Chamber of Commerce):

- Price of goods FOB/FCA Point of departure
- Freight cost CPT/CFR [*Uzbekistan, Nukus*]

8.3. Where installation, commissioning, training or other similar services are required to be performed by the Bidder, the Bidder shall include an itemized list of the prices for those services.

9 Validity of Bid

9.1. The prices of the bid shall be valid for 90 days after the closing date of bid submission as specified by UNFPA. A bid valid for a shorter period shall be rejected by UNFPA on the grounds that it is non-responsive.

9.2. In exceptional circumstances, UNFPA may solicit the Bidder's consent for an extension of the period of validity under exceptional circumstances. The request and the responses shall be made in writing.

D. Submission of Bids and Bid Opening

10 Partial Bids

10.1. Partial bids are allowed under this tender. Bidder can submit quotes for multiple lots, however any lot must be bidden in whole. UNFPA reserves the right to select and accept a part or parts of any bid.

11 Alternative Bids

11.1. Alternative bids will not be accepted. In the event of a supplier submitting more than one bid, the following shall apply:
a. All bids marked alternative bids will be rejected and only the base bid will be evaluated.
b. All bids will be rejected if no indication is provided as to which bids are alternative bids.

12 Bids

12.1. Bids shall be submitted in one envelope or transmitted in an email to a secure email address designated by UNFPA.

12.2. Bids shall be prepared in accordance with Section II: Schedule of Requirements and Technical Specifications and shall include the requested documentation as per Instructions to Bidders Clause 7, and in in accordance with the Price Schedule Form in Section V, 5 of the bid forms.

12.3. Bids shall be signed by the Bidder or a person or persons duly authorized to bind the Bidder to the contract. A bid shall contain no interlineations, erasures, or overwriting except as necessary to correct errors made by the Bidder. In that case such corrections shall be initialled by the person or persons signing the bid.

13 Sealing and Marking of Bids (hard copies)

13.1. When submitting bids in hard copies the Bidder shall prepare one set of sealed bids containing the technical and price components.

13.2. The envelope shall also indicate the name and address of the Bidder to enable the bid to be returned unopened in case it is declared "late."

13.3. If the outer envelope is not sealed and marked as required, UNFPA shall assume no responsibility for the bid's misplacement or premature opening.

13.4. The outer envelope must be clearly marked with the following:

UNITED NATIONS POPULATION FUND (UNFPA)
14, Mahmud Tarobiy Str., Tashkent
Uzbekistan
Invitation to Bid No. UNFPA/UZB/20/001
Attention: Umid Ermanov – Administrative and Finance Associate
ONLY TO BE OPENED BY AUTHORISED UNFPA PERSONNEL

14 Electronic Submissions

14.1. Bids may be submitted electronically. Please note the following guidelines for electronic submissions:

14.2. Bidders shall make clear reference to the specific bid in the subject field as instructed, otherwise bids may be rejected. Clearly specify the following text in the subject line: ITB No. UNFPA*/UZB/20/001*, Bidder's Name.

14.3. The bid shall be submitted rfq.uzb@unfpa.org. Bids received at the rfq.uzb@unfpa.org mailbox are kept undisclosed and shall not be opened before the scheduled opening date. Sending to any other email address will violate confidentiality and invalidate the bid.

14.4. E-mail submission shall not exceed 10 MB, including the size of the cover email. It is recommended that all the bidding documents are consolidated into as few attachments as possible which shall be in commonly used file formats. If the bid consists of large electronic files, it is

recommended to send these files separately before the deadline indicating the order of emails (email 1, email 2, etc.) after the bid reference number and the Bidder's name in the subject line of each email.

14.5. It shall be the Bidder's responsibility to ensure that bids sent by e-mail are received by the deadline. All Bidders shall receive an auto-reply acknowledging the receipt of their email. Bidders shall not receive responses to questions sent to rfq.uzb@unfpa.org since it is a secure mailbox.

14.6. In order to avoid last minute internet congestion it is recommended to send your bid as early as possible before the deadline.

15 Bid Submission Deadline/Late Bids

15.1. Bids must be delivered to the office on or before the date and time specified in the introductory letter of this solicitation document. If any doubt exists as to the time zone in which the bid should be submitted please refer to www.timeanddate.com/worldclock, or contact the bid focal point.

15.2. UNFPA may, under special and exceptional circumstances, extend the bid submission deadline and such changes shall be notified in UNGM before the expiration of the original period.

15.3. Any bid received by UNFPA after the bid submission deadline shall be rejected and returned unopened to the Bidder. UNFPA shall not be legally responsible for bids that arrived late due to the Bidder's problems with transmission of bid submissions via email and/or with the courier company.

16 Storage of Bids

16.1. Bids received prior to the deadline of submission and the time of opening shall be securely kept unopened until the specified bid opening date stated in the UNFPA's solicitation document. No responsibility shall be attached to UNFPA for prematurely opening an improperly addressed and/or identified bid.

17 Bid Opening

17.1. UNFPA shall conduct the bid opening in public at the following address, date and time.

Street Address: *14, Mahmud Tarobiy Str., Tashkent, Uzbekistan*
Floor/ Room number: *2nd Floor*
City: *Tashkent*
Country: *Uzbekistan*
Date: *[7August and 2020]*
Time: *10:00,Uzbekistan time]*, (reference: www.timeanddate.com/worldclock).

17.2. Bids received electronically by the required deadline will be printed and a copy of the bids will be put in a sealed envelope that will be opened at the time and date specified in the bid document. Only the last received bid will be opened if multiple bids are sent by a same Bidder.

17.3. The bids shall be opened publicly at the time and place specified in the ITB and an immediate record made thereof.

17.4. Only those who have submitted bids or their authorized agent or representative may attend the bid opening.

17.5. The report shall be available for viewing by Bidders for a period of thirty days from the date of the opening. No information that is not included in the bid opening report can be given to Bidders.

17.6. No bid shall be rejected at bid opening, except for late bids, which shall be returned unopened to the Bidder.

E. Evaluation and Comparison of Bids

18. Confidentiality

18.1. Information relating to the examination, evaluation, comparison, and post-qualification of bids, and recommendation of contract award shall not be disclosed to Bidders or any other persons not officially concerned with such process until the contract award is published.

18.2. Any effort by a Bidder to influence UNFPA in the examination, evaluation, comparison, and post-qualification of the bids or contract award decisions may result in the rejection of its bid.

19. Clarification of Bids

19.1. To assist in the examination, evaluation and comparison of bids, UNFPA may ask Bidders for clarification of their bids. The request for clarification and the response shall be in writing by UNFPA and no change in price or substance of the bid shall be sought, offered or permitted.

20. Responsiveness of bids

20.1. UNFPA's determination of a bid's responsiveness is to be based on the contents of the bid itself.

20.2. A substantially responsive bid is one that conforms to all the terms, conditions, and specifications of the bidding documents without material deviation, reservation, or omission. A material deviation, reservation, or omission is one that:

a. affects in any substantial way the scope, quality, or performance of the goods and related services specified in the contract; or
b. limits in any substantial way, inconsistent with the bidding documents, UNFPA's rights or the Bidder's obligations under the contract; or
c. if rectified would unfairly affect the competitive position of other Bidders presenting substantially responsive bids.

21. Nonconformities, Errors, and Omissions

21.1. Provided that a bid is substantially responsive:

a. UNFPA may waive any non-conformities or omissions in the bid that do not constitute a material deviation.
b. UNFPA may request that the Bidder submit the necessary information or documentation within a reasonable period of time to rectify non material non conformities or omissions in the bid related to documentation requirements. Such omission shall not be related to any aspect of the price of the bid. Failure of the Bidder to comply with the request may result in the rejection of its bid.

c. UNFPA shall correct arithmetical errors on the following basis:
   - If there is a discrepancy between the unit price and the line item total that is obtained by multiplying the unit price by the quantity, the unit price shall prevail and the line item total shall be corrected, unless in the opinion of UNFPA there is an obvious misplacement of the decimal point in the unit price. In that case the line item total as quoted shall govern and the unit price shall be corrected;
   - if there is a discrepancy between words and figures, the amount in words shall prevail;
   - if there is an error in a total corresponding to the addition or subtraction of subtotals, the subtotals shall prevail and the total shall be corrected; and

22. Preliminary examination of Bids

22.1. UNFPA shall examine the bids to determine whether they are complete, that all documents and technical documentation requested as per Instructions to Bidders Clause 7 have been provided and to determine the completeness of each document submitted. UNFPA will also examine whether any computational errors have been made, whether the documents are properly signed, and whether the bids are generally in order.

23. Examination of Terms and Conditions and Technical Evaluation

23.1. UNFPA shall examine the bid to confirm that it does not contain any material deviations, reservation, or omission related to the conditions and requirements specified in the Section II Technical Specifications and Schedule of Requirements, Section III UNFPA General Conditions of Contract and Section IV UNFPA Special Conditions for Contracts.

23.2. If after the examination of the terms and conditions and the technical evaluation UNFPA determines that the bid is not substantially responsive in accordance with Instructions to Bidders Clause 21, the bid shall be rejected.

24. Conversion to Single Currency

24.1. To facilitate evaluation and comparison, UNFPA will convert all bid prices expressed in the amounts in various currencies in which the bid prices are payable to US dollars at the official UN exchange rate on the last day for submission of bids.

25. Evaluation of Bids

25.1. UNFPA shall evaluate each bid that has been determined, up to this stage of the evaluation, to be substantially responsive.

26. Comparison of Price Bids

26.1. UNFPA shall compare all substantially responsive bids to determine the lowest priced substantially responsive bid

26.2. Bid comparison will be made on the total cost, delivered to final destination. UNFPA reserves the right to compare freight prices of Bidders with rates of reputable freight forwarders and to consider such rates for the purpose of bid evaluation. In the event that Bidder's freight prices are found to be less competitive than the rates offered by freight forwarders, UNFPA may issue a contract on FCA basis to the Vendor instead of CPT/CFR, and issue a separate contract for freight to a freight forwarder if deemed in the best financial interest of UNFPA.

27. Post-qualification of the Bidder

27.1. UNFPA shall determine to its satisfaction whether the Bidder with the lowest priced, substantially responsive bid is qualified to perform the contract satisfactorily.

27.2. The determination shall be based upon an examination of the documentary evidence of the Bidder's qualifications submitted in the bid.

27.3. To evaluate a Bid, UNFPA shall consider the following:

- Copy of last year audited company Balance and Financial Statements
- Copy of valid manufacturing license from the country of manufacturing and/or a copy of company registration in the country of operation demonstrating that is duly authorized to supply these goods to the country of destination

- Financial Capability:
  a. Liquidity ratio: Current ratio (Current Assets/ Current liabilities) > 1.
  b. Provide contact details of commercial banks and names of contact persons from whom UNFPA could seek feedback.
- Experience and Technical Capacity:
  a. Details of experience and past performance of the Bidder on equipments offered and on those of similar nature within the past five years
  b. The Bidder shall disclose instances of previous past performance that may have resulted in adverse actions taken against the Bidder and the manufacturers whose products are being offered by the Bidder, in the last five years. Such adverse actions may be treated as unsatisfactory performance history while deciding the award of contract. If no instance of previous past performance has resulted into adverse actions, this must be clearly indicated in the Bidder's bid.

For non manufacturer Bidders:

a. Legally enforceable authorization from the manufacturer assuring full guarantee and warranty obligations as per the tender conditions for the goods offered; and
b. The Bidder, as authorized by the manufacturers, has supplied and provided after sales service for similar goods to the extent of at least 20 percent of the quantities indicated in the tender requirements in any one of the last three years, and the goods must be in satisfactory operation.

27.4. Notwithstanding anything stated above, UNFPA reserves the right to assess the Bidder's capabilities and capacity to execute the contract satisfactorily before deciding on award.

27.5. Even though the Bidders may meet the above qualifying criteria, they can be subject to disqualification if they have made misleading or false representations in the forms, statements and attachments submitted in proof of the qualification requirements, and/or record of poor performance such as, not properly completing contracts, inordinate delays in completion, litigation history, financial failures, etc.

28. UNFPA's Right to Accept Any Bid and to Reject Any or All Bids

28.1. A bid that is rejected by UNFPA may not be made responsive by the Bidder by correction of the non-conformity. A responsive bid is defined as one which conforms to all the terms and conditions of the UNFPA's bid solicitation documents without material deviations. UNFPA shall determine the responsiveness of each bid against the UNFPA solicitation documents.

28.2. UNFPA reserves the right to reject any bid if a Bidder has previously failed to perform properly or complete on time in accordance with contracts or the Bidder who in UNFPA's perspective is not in a position to perform the contract.

28.3. The Bidders waive all rights to appeal against the decision made by UNFPA.

29. UNFPA's Right to Annul a Bidding Process

29.1. UNFPA reserves the right to annul the bidding process and reject all bids at any time prior to award of purchase order, without thereby incurring any liability to the affected Bidder(s) or any obligation to provide information on the grounds for UNFPA's action.

F. Award of Contract

30. Award Criteria

30.1. In the event of a contract award, UNFPA shall award the *Contract t*o the lowest priced Bidder(s) whose bid has been determined to be substantially responsive with the bidding documents.

30.2. If required, the Bidder shall permit UNFPA representatives' access to their facilities at any reasonable time to inspect the premises that shall be used for the production, testing and packaging of the products. The Bidder shall also provide reasonable assistance to the representatives for such inspection, including copies of any test results or quality control reports as may be necessary. UNFPA may inspect the manufacturing facilities of the lowest evaluated responsive Bidder to assess his capability to successfully perform the contract as per the terms and conditions specified in the ITB.

30.3. UNFPA reserves the right to make multiple arrangements for any item(s) where, in the opinion of UNFPA, the lowest Bidder cannot fully meet the delivery requirements or if it is deemed to be in UNFPA's best interest to do so. Any arrangement under this condition shall be made on the basis of the lowest, second lowest, third lowest, etc., bid which meets the requirements.

31. Right to Vary Requirements at Time of Award

31.2. UNFPA reserves the right at the time of award of contract to increase or decrease by up to 20% the quantity of goods specified in this bid without any change in unit price or other terms and conditions.

32. Signing of the contract

32.1. Prior to the expiration of the period of bid validity, UNFPA shall send the successful Bidder the Contract, which constitute the notification of award. The successful Bidder shall sign, date the contract and return it to UNFPA within 10 days of receipt of the contract. After receipt of the contract, the successful Bidder shall deliver the commodities in accordance with the quantity, quality and delivery schedule outlined in its bid in conjunction with UNFPA terms and conditions.

33. Publication of Contract Award

33.1. UNFPA shall publish the contract award on United Nations Global Marketplace http://www.ungm.org, with the information of the awarded Bidder company name, contract amount or LTA and the date of the contract.

33.2 Suppliers perceiving that they have been unjustly treated in connection with the solicitation or award of a contract may lodge a complaint directly with the UNFPA Head of Office at yu@unfpa.org. The UNFPA Head of Office will then assess the complaint and provide a reply to the supplier within a week. If the supplier is not satisfied with the reply provided by the UNFPA Head of Office, the supplier may escalate the complaint to the Chief, Procurement Services Branch at procurement@unfpa.org, who will reply to the supplier within a week and advise the Supplier on further recourse if required.

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

2. 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*

SECTION III: UNFPA General Conditions of Contract

The General Conditions of Contract can be found at:
http://www.unfpa.org/resources/unfpa-general-conditions-contract

SECTION IV: UNFPA Special Conditions for Contracts

WARRANTY	The warranty period shall be at least 12 months. Details on Warranty Services required are included in Section II: Technical Specifications and Schedule of Requirements.
GOODS AND SERVICES DEFINED	Goods are hereinafter deemed to include, without limitation, equipment, spare parts, commodities, raw materials, components, customized and standard software as required, intermediate products and products which the Supplier is required to supply under the Purchase Order. Services are to include design, installation and commissioning, training services, technical assistance and warranty services as required to supply in the Purchase Order.
AFTER SALES SERVICES	*Installation and Training of Users*
TRANSPORTATION AND FREIGHT	Responsibility for transportation of the Goods shall be as specified in the INCOTERMS. All non-containerized Goods must be shipped below deck Partial shipment *is* allowed. Transhipment *is*allowed.
SHIPPING AND PAYMENT INSTRUCTIONS	Access the following link for shipping and payment instructions: Shipping Instructions
LIQUATED DAMAGES	In the event of a Contract being issued and in case the Vendor fails to deliver all the goods by the date or dates of delivery specified in the Purchase Order, UNFPA reserves the rights to claim liquidated damages from the Vendor and deduct [1%] of the value of the goods pursuant to the Purchase Order per additional week of delay, up to a maximum of 10% of the value of the Purchase Order. The payment or deduction of such liquidated damages shall not relieve the Vendor from any of its other obligations or liabilities pursuant to any current Long Term Agreement or Purchase Order.

SECTION V: Bidding Forms

The following checklist is provided as a courtesy to Bidders. Please use this checklist while preparing the bid to ensure that your bid contains all required information. This checklist is for the Bidder's internal reference and does not need to be submitted with the bid.

ACTIVITY	LOCATION	YES / NO/ NOT APPLICABLE	REMARKS
Have you noted the bid closing deadline?	Cover letter, #5		
Have you read and understood all of the Instructions to Bidders in Section I of the bidding documents?	Section I		
Have you reviewed and agreed to the UNFPA General Conditions of Contract?	Section III		
Have you reviewed and agreed to the UNFPA Special Conditions for Contracts?	Section IV		
Have you completed the Bid Confirmation Form?	Section V, 1		
Have you completed the Bid Submission Form?	Section V, 2		
Have you completed the Bidder's Identification Form?	Section V, 3		
Have you completed the Product Item Overview Form?	Section V, 4		
Have you completed and signed the Price Schedule Form?	Section V, 5		
Have you reviewed all of the relevant contract form(s)?	Section VI		
Have you provided evidence that your firm is established as a company and legally incorporated in the country where it resides?	Section I, Sub-Clause 7.2, a		
Have you prepared a copy of your valid manufacturing license from the country of manufacturing?	Section I, Sub-Clause 7.2, b.		
Have you provided written confirmation that your company is neither suspended by the United Nations system nor debarred by the World Bank Group?	Section I, Sub-Clause 2.4		
Have you prepared documentary evidence that the goods conform to the technical specifications and standards specified in Section II Technical Specifications and Schedule of Requirements?	Section I, Sub-Clause 7.3, a.		
Have you prepared product catalogues containing pictures of the product(s)?	Section I, Sub-Clause 7.3, c.		
Have you prepared the manufacturer's technical product specifications or data sheets?	Section I, Sub-Clause 7.3, d.		
Have you provided the results of any testing carried out on the products?	Section I, Sub-Clause 7.3, a.		
Have you provided any copies of current certificates such as GMP/Quality,	Section I, Sub-Clause 7.3, f.		

FSC/CPP, manufacturer's ISO certificate for the product, manufacturer's CE certificate, USA510k, Japan QS standard, etc. as stated in the Technical Specifications and Schedule of Requirements, in Section II?	
Have you provided a copy of the valid authorization letter issued by the manufacturer for each product, if you are not the manufacturer?	Section I, Sub-Clause 7.3, g.
Have you furnished a list of full particulars, regarding the available sources and current prices of space parts, special tools, etc., necessary for the proper and continuing functions of the goods within the Product Item Overview Form, Section V, 5?	Section I, Sub-Clause7.3, h.
Have you sealed and marked the bids according to Instructions to Bidders Clause 13 (hard copy bids) or Clause 14 (electronic bids)?	Section I, Sub-Clause 13 & 14
If submitted electronically, is the file size of the bid less than 10MB? (If the file size is above 10MB, refer to Instructions to Bidders Sub-Clause 14.4)	Section I, Sub-Clause 14.4
Have you prepared a copy of the previous year's audited company Balance and Financial Statements?	Section I, Sub-Clause 27.3
For non-manufacturer Bidders: Have you provided a legally enforceable authorization from the manufacturer, assuring full guarantee and warranty obligations as per the tender conditions for the goods offered?	Section I, Sub-Clause 27.3, a.
Have you provided evidence that you, as authorized by the manufacturers, have supplied and provided after sales service for similar goods to the extent of at least 20 percent of the quantities indicated in the tender requirements in any one of the last three years, and that the goods are in satisfactory operation?	Section I, Sub-Clause 27.3, b.

1. Bid Confirmation Form

[Complete this page and return it prior to bid opening]

Date:

To: UNFPA — Fax/email: *ermanov@unfpa.org*
[Insert name of Office & contact person]

From: *[Company name]*
[Contact person]
[Telephone]
[Email address]
[Postal address]

Subject: ITB No.: UNFPA*/UZB/20/001*

YES, we intend to submit a bid.

NO, we are unable to submit a bid in response to the above mentioned Invitation to Bid due to the following reason(s):

( ) The requested products and services are not within our range of supply
( ) We are unable to submit a competitive bid for the requested products at the moment
( ) The requested products are not available at the moment
( ) We cannot meet the requested specifications
( ) We cannot offer the requested type of packing
( ) We can only offer FCA prices
( ) The information provided for quotation purposes is insufficient
( ) Your ITB is too complicated
( ) Insufficient time is allowed to prepare a quotation
( ) We cannot meet the delivery requirements
( ) We cannot adhere to your terms and conditions (please specify: payment terms, request for performance security, etc)
( ) We do not export
( ) Our production capacity is currently full
( ) We are closed during the holiday season
( ) We had to give priority to other clients' requests
( ) We do not sell directly, but through distributors
( ) We have no after-sales service available in the recipient country
( ) The person handling bid is away from the office
( ) Other (please specify)

Please confirm one of the following two options:

( ) We would like to receive future ITBs for this type of goods
( ) We don't want to receive ITBs for this type of goods

If UNFPA has questions to the Bidder concerning this NO BID, UNFPA should contact Mr. Umid Ermanov , email : ermanov@unfpa.org, who will be able to assist.

2. Bid Submission Form

[The Bidder shall fill in this form in accordance with the instructions indicated. No alterations to its format shall be permitted and no substitutions shall be accepted.]

Date: *[insert date (as day, month and year) of Bid Submission]*
ITB No.: UNFPA/UZB/20/001

To: Yu Yu, UNFPA CO in Uzbekistan

Dear Sir / Madam,

We the Undersigned have examined and have no reservations to the Bidding Documents No. UNFPA/UZB/2020/001 and amendments We hereby offer to supply, in conformity with the Bidding Documents and in accordance with the Delivery Schedules specified in the Schedule of Requirements, the following goods and related services _____ which are subject to UNFPA General Conditions of Contract and other terms and conditions specified in the document.

We agree to abide by this bid for a period of *90 days* days from the date fixed for opening of bids in the Invitation to Bid, and it shall remain binding upon us and may be accepted at any time before the expiration of that period.

We, including any subcontractors or suppliers for any part of the contract, have nationality from countries_____ *[insert the nationality of the Bidder, including that of all parties that comprise the Bidder, if the Bidder is a JV, and the nationality each subcontractor and supplier; otherwise buyer should delete this text if non-applicable*]

We have no conflict of interest in accordance with Instructions to Bidders Sub-Clause 2.1;

Our firm, its affiliates or subsidiaries—including any subcontractors or suppliers for any part of the contract—have not been declared ineligible by UNFPA, in accordance with Instructions to Bidders Sub-Clause 2.2;

We understand that you are not bound to accept the lowest evaluated bid or any other bid that you may receive.

Dated on .....day of .....[*year*].

Signature:	…… [*insert signature of person whose name and capacity are shown]*
In the capacity of:	…… *[insert legal capacity of person signing the Bid Submission Form]*
Name:	…… *[insert complete name of person signing the Bid Submission Form]*
Company:	…… *[insert name of company]*

3. Bidders Identification Form

Bid No. UNFPA/UZB/20/001

1. Organization

Company/Institution Name	
Address, City, Country	
Telephone/FAX	
Website	
Date of establishment	
Legal Representative: Name/Surname/Position	
Legal structure: natural person/Co.Ltd, NGO/institution/other (please specify)	
Organizational Type: Manufacturer, Wholesaler, Trader, Service provider, etc.	
Areas of expertise of the organization	
Current Licenses, if any, and permits (with dates, numbers and expiration dates)	
Years supplying to UN organizations	
Years supplying to UNFPA	
Production Capacity	
Subsidiaries in the region (please indicate names of subsidiaries and addresses, if relevant to the bid)	
Commercial Representatives in the country: Name/Address/Phone (for international companies only)	

2. Quality Assurance Certification

International Quality Management System (QMS)	
List of other ISO certificates or equivalent certificates	
Presence and characteristics of in-house quality control laboratory (if relevant to bid)	

3. Expertise of Staff

Total number of staff	
Number of staff involved in similar supply contracts	

4. Client Reference List

Please provide references of main client details.

Name of company	Contact person	Telephone	E-mail
1.			
2.			
3.			

5. Contact details of persons that UNFPA may contact for requests for clarification during bid evaluation

Name/Surname	
Telephone Number (direct)	
Email address (direct)	

P.S.: This person must be available during the next two weeks following receipt of bid

4. Product Item Overview Form

LOT 1 Medical Equipment

Item No.	Description and minimum /mandatory specifications	Description of items offered and Bidder's statements on deviations (To be completed by the Bidder)	Compliant? (Y/N) (To be completed by UNFPA during evaluation)
1	**Operating table with accessories**		
2	**Capnograph**		
3	**Doppler ultrasound machine**.		
4	**Electrocoagulation equipment**		
5	**Obstetric table**		

LOT 2 Medical Furniture

Item No.	Description and minimum /mandatory specifications	Description of items offered and Bidder's statements on deviations (To be completed by the Bidder)	Compliant? (Y/N) (To be completed by UNFPA during evaluation)
1	**Medical Examination Couch**		
2	**Stool (rotating)**		
3	**Manipulation table**		
4	**Instrument Cabinet**		
5	**Patient carrying Trolley**		
6	**Anesthesiologist table**		
7	**Mobile surgical instrument table**		
8	**IV infusion stand**		

LOT 3 Obstetric Surgical Instruments

Item No.	Description and minimum /mandatory specifications	Description of items offered and Bidder's statements on deviations	Compliant? (Y/N) (To be completed by UNFPA during evaluation)

		(To be completed by the Bidder)	
1	Hemostatic forceps 1x2 teeth , straight		
2	Hemostatic forceps toothed , curved		
3	Hemostatic forceps toothed , straight		
4	Hemostatic forceps toothed , straight		
5	Heaney Uterine Forceps , curved		
6	Heaney Uterine Forceps , curved		
7	Doyen's Cross Action Towel Clips		
8	MIKULICZ PERITONEAL FORCEPS		
9	Hemostatic forceps, type: -Mosquito, straight		
10	Micro Dissectors Microsurgical		
11	Vaginal retractor (also called vaginal speculum), type: Doyen		
12	Vaginal retractor (also called vaginal speculum), type: Doyen		
13	Vaginal retractor (also called vaginal speculum), type: Doyen		
14	Vaginal retractor (also called vaginal speculum), type: Doyen		
15	Vaginal retractor (also called vaginal speculum), type: Sims		
16	Vaginal retractor (also called vaginal speculum), type: Sims		
17	Vaginal retractor (also called vaginal speculum), type: Sims		
18	Vaginal retractor (also called vaginal speculum), type: Sims		
19	Vaginal retractor (also called vaginal speculum), type: Sims		
20	Fritsch Abdominal Retractor		
21	Fritsch Abdominal Retractor		
22	Kocher Vaginal Retractor		
23	Kocher Vaginal Retractor		
24	Otto Vaginal Retractor		
25	Abdominal Retractors type: Fritsch-Doyen		
26	Doyen Surgical Probes		
27	Urinary catheters , metal , for female, curved No 14		
28	Urinary catheters , metal , for female, curved No 17		
29	Korntsang curved		
30	Korntsang straight		
31	Volkmann Retractor 4 Prong Sharp		
32	Volkmann Retractor 4 Prong Blunt		
33	Curette Uterine Sharp		

34	Curette Uterine Blunt		
35	Curette Uterine Blunt		
36	Curette Uterine Blunt		
37	RETRACTOR/SPATULA, REVERDIN		
38	UMBILICAL CORD SCISSORS CURVED SIDEWARDS		
39	Blot's Perforator		
40	Brunner Abdominal Retractor		
41	Forceps, intestinal, Duval (tweezer)		
42	Russian Tissue Forceps		
43	Forceps,tissue,standard,dissecting,1x2 teeth		
44	Forceps,tissue,standard,dissecting,1x2 teeth		
45	Retractor/spatula, abdominal, Reverdin		
46	Retractor, abdominal, Frisch		
47	Corkscrew for grasping fibromyoma		
48	Forceps uterine 2x2 straight : Museux		
49	Forceps uterine 2x2 straight type :Museux		
50	Uterine Polypus Forceps With Fenestrated Serrated Jaws		

LOT 4 Glucometer

Item No.	**Description and minimum /mandatory specifications**	**Description of items offered and Bidder's statements on deviations** (To be completed by the Bidder)	**Compliant? (Y/N)** (To be completed by UNFPA during evaluation)
1	**Glucometer-express method**		

LOT 5 Medical Compressor and Console

Item No.	**Description and minimum /mandatory specifications**	**Description of items offered and Bidder's statements on deviations** (To be completed by the Bidder)	**Compliant? (Y/N)** (To be completed by UNFPA during evaluation)
1	**Medical Console**		
2	**Medical Compressor**		

5. Questionnaire for Electrical or Battery Operated Equipment

PART I – Bidder and device identification

Device Identification (Trade name, Type, Model, Product code, Reference(s)):

Identification of the bidder:

Name:
Address:
Status:
Legal manufacturer:
or
Distributor – Trader:
If the Submitter is not the legal manufacturer, then indicate the legal manufacturer:

Device category: (Generic group of devices):

Device classification (specify the related regulation, e.g. MDD, FDA, Other)

93/42/EEC directive:
Class: Rule# (according to MDD annex IX):
FDA:
Product code:
Regulation number:
Product class:
Other regulation (specify):

Nomenclature code (if known – specify GMDN, UMDNS or other):

PART II – Quality Management System Certification

Legal Manufacturer:

1. ISO 9001 ☐ Yes ☐ No
   a. Certification body:
   b. Expiration date:

2. ISO 13485 ☐ Yes ☐ No
   a. Certification body:
   b. Expiration date:

3. ISO 14001 or plans for this ☐ Yes ☐ No
   a. Certification body:
   b. Expiration date:

4. ISO 50001 or plans for this ☐ Yes ☐ No
   a. Certification body:
   b. Expiration date:

If the manufacturing process(es) is(are) subcontracted:

Subcontracted activity / process	Name / address of the sub-contractor	QMS certification of the subcontractor

Bidder (if the bidder is not the legal manufacturer):

1. ISO 9001 ☐ Yes ☐ No
   a. Certification body:
   b. Expiration date:

2. ISO 13485 ☐ Yes ☐ No
   a. Certification body:
   b. Expiration date:

PART III – Regulatory certification

Is the device EC marked? ☐ Yes ☐ No

For devices other than Class I, and Class I sterile devices / Class I with measuring function:
Nature of the EC certification (MDD 93/42/EEC):
☐ Annex II.3 ☐ Annex V

Identification of the Notified Body (+ identification number):

Is the device FDA approved? ☐ Yes ☐ No

For FDA Class I device:
Manufacturer name:
Manufacturer listing #:

If the device is "510k cleared", indicate the 510k clearance #:

Other regulatory clearance / registration (specify Canada, Japan, Australia, …):

Applicable regulation:
Certification / license number:

If the device contains lithium metal and lithium ion batteries

- Does it comply with clause 38.3 of the recommendations on "Transport Of Dangerous Goods" from the United Nations? ☐ Yes ☐ No
- Does it comply with the latest IATA Dangerous Goods Regulations (DGR)? ☐ Yes ☐ No

PART IV – compliance to technical standards

If the declaration of compliance is based on report(s) issued by an independent testing laboratory, the reference of the test report must be indicated (mandatory for safety compliance of electro-medical devices)

Standard # and date	Fully or partially applied	Identification of the Testing laboratories, where used	Test report reference

Part V – Other information

V-1 INSTALLATION / SPARES / SERVICE

1. Is installation necessary ☐ Yes ☐ No
   Specify tools required (if Yes):

2. Is training required? ☐ Yes ☐ No
   Specify who will provide training and specify costs if applicable:

3. Are spare parts available? ☐ Yes ☐ No
   Specify source and if additional costs required:
   Specify period supply of spare parts is guaranteed:

4. Information available on service/maintenance? ☐ Yes ☐ No
   Attach information:

5. Specify voltage and frequency available:
   Specify plug supplied:

V-2 DECONTAMINATION (Only for re-usable devices)

Specify method for cleaning:

Specify instructions for disinfection:

Specify any restrictions on detergent/disinfectant types:

Specify sterilization method required before re-use:

V-3 WARRANTY

Specify recommended maximum number of uses or years of use or period of use:

V-4 SAFE DISPOSAL

Specify instructions for safe disposal:

6. Questionnaire for Medical Device/Equipment

All documents submitted must be in English or be accompanied with certified translation.

PART I – Submitter and manufacturer information

Submitter:

Name of submitter: Click here to enter text.
Address: Click here to enter text.
Contact person's name: Click here to enter text.
Email: Click here to enter text.
Phone: Click here to enter text.

Status of the submitter:

Legal manufacturer Yes ☐ No ☐
or
Distributor – Trader Yes ☐ No ☐

Legal manufacturer:

Name of manufacturer: Click here to enter text.
Country: Click here to enter text.

Address (office): Click here to enter text.
Address (manufacturing site(s)): Click here to enter text.
Contact person's name: Click here to enter text.
Email: Click here to enter text.
Phone: Click here to enter text.

PART II – Device identification

Device Identification (Trade name, Type, Model, Product Code, Reference(s))**:**
Click here to enter text.
Intended use / purpose:
Click here to enter text.
Product details (material, dimensions, etc.)**:**
(E.g. If stainless steel product, identify AISI type or composition. If plastic product, identify grade or composition)
Click here to enter text.

Device classification (specify the related regulation, e.g. MDD, FDA, Other)
EU 93/42/EEC directive, Rule# (according to MDD annex IX)
Class: Click here to enter text.
FDA:
Product code: Click here to enter text.
Regulation number: Click here to enter text.
Product class: Click here to enter text.
Other regulation (specify): Click here to enter text.
Nomenclature code (if known – specify GMDN, UMDNS or other): Click here to enter text.

Part III – Quality Management System Certification

Legal Manufacturer:

1. ISO 9001 Yes ☐ No ☐
   a. Certification body: Click here to enter text.
   b. Expiration date: Click here to enter text.

2. ISO 13485 Yes ☐ No ☐
   a. Certification body: Click here to enter text.
   b. Expiration date: Click here to enter text.

3. ISO 14001 or plans for this Yes ☐ No ☐
   a. Certification body: Click here to enter text.
   b. Expiration date: Click here to enter text.

4. ISO 50001 or plans for this Yes ☐ No ☐
   a. Certification body: Click here to enter text.
   b. Expiration date: Click here to enter text.

If the manufacturing processes are subcontracted:

Subcontracted activity / process	Name / address of the subcontractor	QMS certification of the subcontractor
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.

Submitter (if the submitter is not the legal manufacturer):

1. ISO 9001 Yes ☐ No ☐

a. Certification body: Click here to enter text.
b. Expiration date: Click here to enter text.

2. ISO 13485 Yes ☐ No ☐
   a. Certification body: Click here to enter text.
   b. Expiration date: Click here to enter text.

Part IV – Regulatory certification

Is the **device CE marked?** Yes ☐ No ☐

For devices other than Class I excluding Class I sterile devices / Class I with measuring function / Class I reusable surgical instruments

Nature of the EC certification (MDD 93/42/EEC): Annex II.3 ☐ Annex V ☐

Identification of the Notified Body (+ identification number): Click here to enter text.

Is the device **FDA** approved? Yes ☐ No ☐

For FDA approved device: Manufacturer name: Click here to enter text.

Manufacturer listing #: Click here to enter text.

If the device is "510k cleared", indicate the 510k clearance #: Click here to enter text.

If the device is "PMA cleared", indicate the PMA clearance #: Click here to enter text.

Other regulatory clearance / registration (specify Canada, Japan, Australia): Click here to enter text.

Applicable regulation: Click here to enter text.

Certification / license number: Click here to enter text.

Part V – Compliance to technical standards

If the declaration of compliance is based on report(s) issued by an independent testing laboratory, the reference of the test report must be indicated (mandatory for safety compliance of electro-medical devices)

Standard # and date	Fully or partially applied	Identification of the Testing laboratories, where used	Test report reference
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.

Part VI – Other information

VI-1 INSTALLATION / SPARES / SERVICE

1. Is installation necessary? Yes ☐ No ☐

   Specify tools required (if Yes): Click here to enter text.
2. Is training required? Yes ☐ No ☐

   Specify who will provide training and specify costs if applicable: Click here to enter text.
3. Are spare parts available? Yes ☐ No ☐

   Specify source and if additional costs required: Click here to enter text.

   Specify period supply of spare parts is guaranteed: Click here to enter text.
4. Information available on service/maintenance? Yes ☐ No ☐

   Attached information: Click here to enter text.
5. Electrical Medical Device/Equipment Yes ☐ No ☐

   Specify voltage and frequency available: Click here to enter text.

   Specify all plug types available: Click here to enter text.

VI-2 DECONTAMINATION

Only for re-usable devices.

1. Specify method for cleaning: Click here to enter text.
2. Specify instructions for disinfection: Click here to enter text.
3. Specify any restrictions on detergent/disinfectant types: Click here to enter text.
4. Specify sterilization method required before re-use: Click here to enter text.

VI-3 WARRANTY

Specify recommended maximum number of uses or years of use or period of use:
Click here to enter text.

VI-4 SAFE DISPOSAL

Specify instructions for safe disposal: Click here to enter text.

Checklist of Required documentation:

Documents to be submitted must be true and valid copies.

☐ Copy of manufacturing licence
☐ Letter of authorization to act on behalf of manufacturer if submission is not from the manufacturer
☐ Copy of ISO 9001 certificate (for manufacturer and for trader)
☐ Copy of ISO 13485 certificate (for manufacturer and for trader)
☐ Complete and detailed technical specifications of the product (incl. **manufacturer's product code**)
☐ **CE certificate** (additionally for EC class III items EC Design Dossier)
☐ Declaration of conformity (signed and dated, according to ISO 17050, specifying the relevant directives, regulations and standards, and attaching copy of certificates)
☐ Manufacturer's EC Representative (EC Rep) contact details and country information
☐ **FDA 510k Premarket approval device letter/ Device licence (Australia, Japan, Canada)**
☐ Evidence that product has been sold to Europe or U.S. or other large market areas with strong regulatory systems.
☐ Evidence of clinical studies to all but class I non-sterile, non-measuring medical devices: e.g. a copy of study results
☐ Product technical data sheet
☐ **Photos of the product, packaging and labelling** at various angles if necessary
☐ Instruction for use in English, Spanish and French
☐ User, installation and/or assembly manual, if applicable
☐ Service/repair (after sale) services with contact details, if applicable
☐ Information on cleaning, disinfecting and sterilization methods (for reusable devices only)
☐ Certificates for product-specific safety standards, such as ISO 10993-1.
☐ Certificate for sterilization process, such as ISO 17665 (Steam sterilization), ISO 11135 (ETO sterilization), ISO 11137 (Gamma Irradiation), or other equivalent.
☐ Manufacturer's Post-market study report from 3 last years
☐ Quality Assurance process (for the manufacturer and/or for the trader)

S. Specify any other documentation provided (e.g. any test results or relevant standards):

☐ ISO 14001. If not available, a signed commitment letter from a manufacturer
☐ Other relevant certificates related to Environmental and/or Energy management, such as ISO 50001, or FSC certificates for the carton and paper used in packaging (for manufacturer and for trader).
☐ Manufacturer's copy of the latest audit report (audited by an European health product distributor)
☐ Copy of third party laboratory test reports, if available (Laboratory name and ISO 17025 accreditation status), if applicable.

7. Price Schedule Form

BIDDER'S TOTAL PRICES (Price & Currency to be entered by Bidder):	
TOTAL FIRM FCA PRICE	
TOTAL FIRM CPT/CFR [*delete unwanted option*,] PRICE	
TOTAL PRICE FOR SERVICES *(if applicable)*	
FREIGHT COST PER 20/40 FT CONTAINER *(if applicable)*	

BIDDER'S PRICES FOR GOODS (Price & Currency to be entered by Bidder):						
ITEM/ LOT	DESCRIPTION OF THE GOODS	QTY (a)	CURRENCY: UNIT PRICE FCA (b)	UNIT PRICE CPT (c)	TOTAL PRICE FCA (a)x(b)	TOTAL PRICE CPT (a)x(c)
1.						
2.	*Insert more rows if necessary*					
3.	*or delete if too many*					
4.						
5.						

BIDDER'S PRICES FOR SERVICES (Price & Currency to be entered by Bidder):					
ITEM/ LOT	DESCRIPTION OF THE SERVICES	COUNTRY OF ORIGIN	QUANTITY AND PHYSICAL UNIT (a)	UNIT PRICE (b)	TOTAL PRICE PER SERVICE (a)x(b)
1.	e.g. Comprehensive Annual Maintenance Contract				
2.	*Insert more rows if necessary*				
3.	*or delete if too many*				
4.					
5.					

BIDDER'S DELIVERY DATA		
Country of origin of offered products:	Item 1	
	Item 2	*Insert more rows in each section if necessary*

	Item 3	*or delete if too many*			
FCA point(s) of delivery for offered products:	Item 1				
	Item 2				
	Item 3				
Delivery time (FCA from date of order):	Item 1				
	Item 2				
	Item 3				
Shipment dimensions of offered products (including package):		Gross weight	Total volume	*Containers (if applicable):*	
				Number	*Size*
	Item 1				
	Item 2				
	Item 3				
	Total				

BIDDER'S SIGNATURE AND CONFIRMATION OF THE ITB

PROVIDED THAT A PURCHASE ORDER IS ISSUED BY UNFPA **WITHIN THE REQUIRED BID VALIDITY PERIOD**, THE UNDERSIGNED HEREBY COMMITS, SUBJECT TO THE TERMS OF SUCH PURCHASE ORDER, TO FURNISH ANY OR ALL ITEMS AT THE PRICES OFFERED AND TO DELIVER SAME TO THE DESIGNATED POINT(S) WITHIN THE DELIVERY TIME STATED ABOVE.

Exact name and address of company

COMPANY NAME_____

ADDRESS_____

_____

PHONE NO._____ FAX NO. _____

EMAIL ADDRESS OF CONTACT PERSON_____

OTHER EMAIL ADDRESSES_____

AUTHORIZED SIGNATURE **DATE**

NAME OF AUTHORIZED SIGNATORY (TYPE OR PRINT)

FUNCTIONAL TITLE OF SIGNATORY

WEB SITE_____