

Template Emergency ITB document



United Nations Population Fund (UNFPA)
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Date: 08th November 2024

Invitation to Bid (ITB) No. UNFPA-PAL-ITB-2024-012

RH Pharmaceuticals & Medical Supplies

Dear Sir/Madam,

We hereby solicit your Bid for the supply and delivery of the following items with the following technical specifications as stated in **Annex 6**:

LOT #1 – Pharmaceuticals

Item No.	Item	Unit of Measure	Estimated Quantity
1	Povidone iodine 10% solution for cutaneous use, 500ml bottle	Bottle	400
2	Ferrous III as polymaltose complex (50mg/ml elemental iron)15ml drops.	Bottle	10,000
3	Ibuprofen 400mg tablet	Pack of 500	200
4	Metronidazole 250mg tablet	Pack of 1000	226
5	anti-D (RhO) immunoglobulin 300mcg (winrho SDF)	Vial	1,200
6	Iron 60mg+Folic Acid 0.4 Tablets Ferrous fumarate /Folic acid coated 185mg (60mg/0.4mg)	Pack of 100	30,000
7	Paracetamol 500mg tablets	Pack of 1000	1,225
8	Calcium carbonate 600 mg Chewable Tablet	Pack of 1000	952
9	Hydralazine 20mg I.M. I.V. 2 ml Hydralazine hydrochloride 20mg/2ml powder for injection in 2ml ampoule	Ampoule	1,200
10	Methylethylamphetamine 0.2 mg	Tab	4,000
11	Dexamethasone sodium phosphate 4mg base/ml in 1ml ampoule	Pack of 100	120

Item No.	Item	Unit of Measure	Estimated Quantity
12	Multivitamin coated tablets for pregnant women Minimum required ingredients: Folic Acid, Iron, Calcium, Vitamin D, Iodine, Vitamin B12, Vitamin C, Omega-3 Fatty Acids, and Zinc.	Pack of 1000	1,000
13	Alprostadil (PGE1) 0.5 mg / ml , 1 ml	Ampoule	600
14	Enoxaparin prefilled syringes 60 mg/ml (Clexane) Enoxaparin 60mg/0.6ml injection, pre-filled syringe	Pre-filled syringe	4,000
15	Vitamin K1, injection, 1 mg/ml, 1-ml vial Vitamin K1 (phytomenadione) 1mg/ml injection	Ampoule	7,080
16	Tranexamic acid, injection, 100 mg/ml, 10-ml ampoule	Ampoule	3,280
17	Ergometrine maleate 0.2mg base/ml injection in 1ml ampoule	Ampoule	3,000
18	Heparin sodium 5000 IU/ml 5 ml. Specifications: Heparin 5000IU/ml inj, 5ml vial/PAC-10	Vial	8,000
19	Nifedipine (Oral Route) 30 mg, tab	Tab	2,000
20	Nifedipine (Oral Route) 60 mg, tab	Tab	2,000
21	Azithromycin 250 mg, tablet	Pack of 1000	225
22	Azithromycin dihydrate 200 mg base/5-ml suspension, 15-ml bottle Product Specifications: Azithromycin pdr/or s 200mg/5ml/BOT-15ml	Bottle	2,730
23	Cefixime 200 mg, tablet	Tab	43,340
24	Cefixime trihydrate 100 mg/5-ml powder for oral suspension, 30 ml	Bottle	4,240
25	Lamivudine 300 mg + tenofovir 300 mg, tablet Lamivudine 300mg + Tenofovir Disoproxil Fumarate 300mg Tablets	Tab	16,200
26	Atazanavir (ATV) 300 mg + ritonavir (r) 100 mg, tablet	Tab	16,200
27	Lamivudine 30 mg + zidovudine 60 mg, tablet	Tab	25,920
28	Lopinavir (LPV) 200 mg + ritonavir (r) 50 mg, tablet	Tab	4,320
29	Lopinavir (LPV) 100 mg + ritonavir (r) 25 mg, tablet	Tab	6,480
30	Benzathine benzylpenicillin 1.44 g (2.4 MIU), 5-ml vial	Vial	5,720
31	Benzathine benzylpenicillin 900 mg (1.2 MIU), 5-ml vial	Vial	880

Item No.	Item	Unit of Measure	Estimated Quantity
32	Water for injection, sterile, 10-ml ampoule Water for injection in 10ml plastic ampoule	Ampoule	40,800
33	Clotrimazole 500 mg + applicator, vaginal tablet	Tab	8,800
34	Ampicillin sodium 500 mg, powder for injection in vial Ampicillin as sodium salt powder for injection 500mg vial	Vial	26,400
35	Gentamicin sulfate 40-mg base/ml for injection in 2-ml ampoule	Ampoule	11,800
36	Clindamycin, injection, 600mg (as phosphate)/4-ml ampoule Clindamycin solution 150mg/ml (as phosphate) packed in 4ml ampoule	Ampoule	21,900
37	Amoxicillin, powder for oral suspension, 125 mg/5 ml, 100-ml bottle Amoxicillin powder for oral suspension 125mg/5ml 100 ml bottle.Child resistant packaging and closure plastic bottle.	Bottle	520
38	Misoprostol 200 µg, tablet	Tab	20,640
39	Ferrous fumarate 185 mg (60 mg iron)/folic acid 0.4 mg, tablet	Tab	380,000
40	Tetracycline hydrochloride 1%, eye ointment, 5-g tube	Tube	1,296
41	Lidocaine hydrochloride 1%, 20-ml ampoule USP or BP or equivalent	Ampoule	6,000
42	Oxytocin 10 IU/ml for injection in 1-ml ampoule (keep cold: 2–8°C)	Ampoule	21,600
43	Sodium lactate (Ringer's lactate), IV infusion, 1 litre + giving set Sodium lactate compound solution (Ringers lactate) solution for infusion 1000ml bottle with an infusion-giving set sterile single use.Plastic bottle compliant with USP. Cap - E	Bottle	8,160
44	Glucose 5%, isotonic, 1 litre + infusion set, sterile, single use	Bottle	10,480
45	Magnesium sulfate 500 mg/ml for injection in 10-ml ampoule	Ampoule	3,560
46	Hydralazine hydrochloride 20 mg/2 ml for injection in 2-ml ampoule Hydralazine hydrochloride 20mg/2ml powder for injection in 2ml ampoule	Ampoule	4,728
47	Calcium gluconate 100 mg base/ml for injection in 10-ml ampoule	Ampoule	2,640
48	Vitamin K, injection, 2 mg/0.2-ml vial	Vial	3,800
49	Sodium chloride 0.9%, injection, 10-ml ampoule	Ampoule	8,880
50	Chlorhexidine gluconate 4% solution (Hibiscrub), 500-ml bottle	Bottle	748
51	Povidone-iodine 10% solution for cutaneous use, 1-litre bottle	Bottle	1,220
52	Cloxacillin, powder for solution (IV/IM), 500-mg vial	Vial	2,520

Item No.	Item	Unit of Measure	Estimated Quantity
53	Glucose 10%, injection, 10-ml ampoule	Ampoule	3,360
54	Epinephrine (adrenaline), injection, 1 mg/ml, 1-ml ampoule	Ampoule	280
55	Bupivacaine hydrochloride (as anhydrous) 0.5%, intrathecal injection, 5 mg/ml, 10-ml ampoule	Ampoule	2,800
56	Atropine sulfate 1 mg/ml for injection in 1-ml ampoule	Ampoule	560
57	Ephedrine hydrochloride, 30 mg/ml for injection in 1-ml ampoule	Ampoule	4,200
58	Ketamine hydrochloride 50 mg base/ml for injection in 10-ml vial	Vial	1,400
59	INSULIN ASPART 100 IU/ML 3 ML PREFILLED PENS	Single	5,224
60	METFORMIN 850MG TAB	Th	4,556
61	AMPICILLIN 1 G VIAL Ampicillin sodium 1000mg (1g) powder for solution for injection in vial	Single	8,066
62	DEXT.50% SOLN 500ML	Single	1,060
63	METHOTREXATE SOD. 50 MG VIAL Methotrexate 50mg solution for injection, vial	Single	1,250
64	Levothyroxine 100mcg tablets	Th	322
65	fluconazole 2mg/ml 50 ml vial	Single	1,284
66	RAPID ACTING INSULINE ANALOGUE 100 U/ML 3ML PFP	Single	42,608
67	ASPIRIN 100MG TAB	Th	3,008
68	FERROUS SLF160MG (50 mg iron)+FOLIC ACID 400MCG TAB	Th	1,196
69	PREDNISOLONE 20MG TAB	Th	74
70	OMEPRazole 20MG TAB OR CAP	Th	1,454
71	Levothyroxine 50mcg tablets	Th	254

Notes:

- UNFPA preserves the right to adjust (increase/decrease) quantities without incurring any additional charges.

LOT #2, 3 and 4 – Medical Supplies (Please refer to the Pricing Schedule for the content of each LOT)

The medical supplies listed below are grouped into LOTs, with each LOT representing a specific category. Bidders may submit offers for one or more LOTs, under the condition that the Bidder must provide prices for at least 80% of the items in each LOT.

Item No.	Item	UoM	Quantity	Category
1	Gloves, surgical, size 7,5, powder-free, sterile, single use	Pair	30,000	Disposables
2	Gloves, surgical, size 8, powder-free, sterile, single use,	Pair	46,120	Disposables
3	Gloves, exam, latex, non-sterile, single use, (large size)	Pair	10,000	Disposables
4	Gloves, exam, latex, non-sterile, , single use, (medium size)	Pair	47,400	Disposables
5	Operation room face mask disposable, made of non tranmitant fabric material, not paper	Piece	60,000	Disposables
6	Disposable medical gown	Piece	60,000	Disposables
7	Umbilical Cord Clamp	Piece	5,000	Disposables
8	Vaginal Speculum (Large) Plastic	Piece	1,500	Disposables
9	Vaginal Speculum (Medium) Plastic	Piece	1,500	Disposables
10	Vaginal Speculum (Small) Plastic	Piece	1,500	Disposables
11	Vaginal Speculum (Large)	Piece	500	Surg. Instrument
12	Vaginal Speculum (Medium)	Piece	500	Surg. Instrument
13	Vaginal Speculum (Small)	Piece	500	Surg. Instrument
14	Bed sheet, cotton or cotton blend (majority cotton), single-bed, 220 x 110 cm	Piece	2,000	Bedding
15	Disposable Waterproof Non-Woven Fabric Bed Sheet for Patients, Hospital Bed, Adults (Standard size)	Piece	3,000	Bedding
16	Hand Sanitizer, Alcohol 70-80%, 0.5 Ltr	Bottle	5,000	IPC
17	Sharps container, 3-5 L, cardboard	Box	1,000	IPC
18	HemoCue Hb 201 Microcuvettes, Strip <i>(IVD Product - See required documentation)</i>	Box of 50	500	Laboratory
19	HemoCue Hb 301 Microcuvettes <i>(IVD Product - See required documentation)</i>	Box of 50	500	Laboratory
20	Placenta Pan / basin, stainless steel, 600-800 CC, with cover	Piece	100	Instruments

Item No.	Item	UoM	Quantity	Category
21	Ambu Bag, neonatal, 200–320 mL. Intake valve with optional nipple for O2 tubing: polycarbonate/ polysulfone or other material fulfilling the ISO 10651-4 or equivalent.	Piece	50	Instruments
22	Paper CTG, Thermal, Z-fold P4,	Stack	300	Medical Stationary
23	Autoclave Tape-Sterilization Tape (3/4" Wide) 50m	Roll	1,000	Medical Stationary
24	Syringe, Luer, 2 ml, sterile, single use	Each	62,400	Disposables
25	Needle, Luer, 21G, sterile, single use	Each	235,200	Disposables
26	Cotton wool, 500 g, roll, non-sterile	Roll	732	Disposables
27	Syringe,disp,5ml,ster/BOX-100	Box of 100	228	Disposables
28	Tourniquet, latex rubber, 75 cm	Each	152	Disposables
29	Clamp, umbilical, 5.2 cm, sterile, single use	Each	13,200	Disposables
30	Cannula, IV short, 20G, sterile, single use	Each	21,600	Disposables
31	Syringe,disp,10ml,ster/BOX-100	Box of 100	632	Disposables
32	Syringe,disp,1ml,ster/BOX-100	Box of 100	264	Disposables
33	Needle, Luer, 25G, sterile, single use	Each	29,200	Disposables
34	Syringe, feeding, catheter tip, 50 ml, sterile, single use	Each	760	Disposables
35	Gloves, surgical, size 7, powder free, sterile, single use	Each	16,120	Disposables
36	Gloves, gynaecological, medium, powder free, sterile	Each	660	Disposables
37	Suture, absorbable, DEC3(2-0), 3/8, 30 mm, round, sterile	Each	2,736	Disposables
38	Extractor, mucus, 20 ml, sterile, single use	Each	3,800	Disposables
39	Tube, suction, CH10, 50-cm long, conical tip, sterile	Tube	2,440	Disposables
40	Tube, suction, CH14, 50-cm long, conical tip, sterile	Tube	2,440	Disposables
41	Catheter, urethral, CH12, sterile	Each	1,520	Disposables
42	Gauze, compress, 10 × 10 cm, sterile	Each	62,000	Disposables
43	Tape, adhesive, zinc oxide, 2.5 cm × 5 m	Each	1,780	Disposables
44	Suture, absorbable, DEC4(1), 3/8, 36 mm, triangular, sterile	Each	10,080	Disposables
45	Suture, absorbable, DEC3(2-0), 1/2, 30 mm, round, sterile	Each	9,744	Disposables

Item No.	Item	UoM	Quantity	Category
46	Suture, absorbable, DEC3(2-0), 3/8, 50 mm, round, sterile	Each	2,016	Disposables
47	Syringe, 0.5 ml, permanently attached needle, sterile, single use	Each	3,080	Disposables
48	Disinfectant tablet for water containing 1.67 g of sodium dichloroisocyanurate (NaDCC)	Tab	11,200	Disposables
49	Cannula, IV short, 18G, sterile, single use	Each	2,800	Disposables
50	Syringe, Luer lock, 20 ml, sterile, single use	Each	2,800	Disposables
51	Needle, Luer, 23G, sterile, single use	Each	2,800	Disposables
52	Needle, scalp vein, butterfly, 25G, sterile, single use	Each	5,600	Disposables
53	Suture, non-absorbable, DEC3(2-0), 3/8, triangular, 30 mm, sterile	Each	4,032	Disposables
54	Catheter, urethral, Foley, CH14, sterile	Each	4,200	Disposables
55	Bag, urine, collecting, 2 litres	Each	4,200	Disposables
56	Needle, spinal, 22G, sterile, single use	Each	3,360	Disposables
57	Tape, adhesive, zinc oxide, perforated, 10 cm × 5 m	Each	140	Disposables
58	Blade, scalpel, sterile, single use, no. 22	Each	2,800	Disposables
59	Basin, kidney, stainless steel, 825 ml	Each	152	Instruments
60	Tray, instruments, stainless steel, 22.5 × 12.5 × 5 cm	Each	76	Instruments
61	Scissors, Mayo, 14 cm, curved, blunt/blunt	Each	152	Instruments
62	Scissors, gynaecological, 20 cm, curved, blunt/blunt	Each	180	Instruments
63	Timer, 60 minutes, mechanical	Each	76	Instruments
64	Drum, sterilizing, diameter 165 mm	Each	152	Instruments
65	Drum, sterilizing, diameter 260 mm	Each	152	Instruments
66	Drum, sterilizing, diameter 290 mm	Each	152	Instruments
67	Flashlight, frontal, LED, battery operated, including batteries	Each	76	Instruments
68	Scissors, Mayo, 17 cm, curved, blunt/blunt	Each	56	Instruments
69	Needle holder, Mayo-Hegar, 18 cm, straight	Each	56	Instruments
70	Retractor, vaginal, Doyen, 8.5 × 4.5 cm	Each	56	Instruments
71	Speculum, vaginal, Graves, 75 × 20 mm	Each	28	Instruments
72	Speculum, vaginal, Graves, 95 × 35 mm	Each	28	Instruments

Item No.	Item	UoM	Quantity	Category
73	Speculum, vaginal, Graves, 115 × 35 mm	Each	28	Instruments
74	Forceps, dressing, Cheron, 25 cm	Each	112	Instruments
75	Tray, instruments, stainless steel, 32 × 20 × 8 cm, with cover	Each	28	Instruments
76	Clamp, towel, Backhaus, 120 mm	Each	112	Instruments
77	Forceps, artery, Kelly, 14 cm, curved	Each	280	Instruments
78	Forceps, artery, Halsted-Mosquito, 12.5 cm, curved	Each	168	Instruments
79	Forceps, artery, Kocher, 14 cm, straight	Each	56	Instruments
80	Forceps, artery, Rochester-Pean, 20 cm, curved	Each	56	Instruments
81	Forceps, artery, Rochester-Pean, 24 cm, curved	Each	56	Instruments
82	Forceps, artery, Mixter, 23 cm	Each	28	Instruments
83	Forceps, dressing, standard, 145 mm, straight	Each	28	Instruments
84	Forceps, dressing, standard, 250 mm, straight	Each	28	Instruments
85	Forceps, intestinal clamp, Doyen, 23 cm, curved	Each	28	Instruments
86	Forceps, uterine, Phaneuf, 21.5 cm, curved	Each	56	Instruments
87	Forceps, uterine, Duplay, 28 cm, curved	Each	28	Instruments
88	Forceps, tissue, Allis, 4 × 5 teeth, 15 cm	Each	56	Instruments
89	Forceps, tissue, Babcock, 20 cm	Each	28	Instruments
90	Forceps, tissue, Duval, 23 cm	Each	56	Instruments
91	Forceps, tissue, standard, 145 mm, straight	Each	28	Instruments
92	Forceps, tissue, standard, 250 mm, straight	Each	28	Instruments
93	Bowl, stainless steel, 500 ml	Each	28	Instruments
94	Retractor, abdominal, Collin, three blades	Each	28	Instruments
95	Retractor, abdominal, Balfour, three blades	Each	28	Instruments
96	Retractor, double-ended, Farabeuf, 15 cm, pair	Pair	28	Instruments
97	Scalpel handle no. 4, blade holder, 13 cm	Each	28	Instruments
98	Scissors, Metzenbaum/Nelson, 18 cm, curved, blunt/blunt	Each	28	Instruments
99	Scissors, Metzenbaum/Nelson, 23 cm, curved, blunt/blunt	Each	28	Instruments

Item No.	Item	UoM	Quantity	Category
100	Scissors, Mayo, 23 cm, curved, blunt/blunt	Each	28	Instruments
101	Spatula, Ribbon retractor, malleable, 27 × 250 mm	Each	28	Instruments
102	Tube, suction, Yankauer, 28 cm	Each	28	Instruments
103	Cranioclast, Braun, 420 mm	Each	28	Instruments
104	Perforator, Smellie, 25 cm	Each	28	Instruments
105	Hook, decapitation, Braun, 31 cm	Each	28	Instruments
106	Bowl, stainless steel, 180 ml	Each	28	Instruments
107	Chlorhexidine digluconate 5% solution, 1-litre bottle	Bottle	2,196	IPC
108	Safety box, disposal of used syringes and needles, 5 litres	Each	2,348	IPC
109	Brush, hand, scrubbing, plastic	Each	432	IPC
110	Glasses, safety, regular size, disposable	Each	208	IPC
111	Apron, protection, plastic, reusable	Each	152	IPC
112	Draw sheet, plastic, 90 × 180 cm, reusable	Each	152	IPC
113	Bag, biohazard, yellow, 50 litres	Each	8,000	IPC
114	Basket, instruments, for sterilization, wired, 400 × 200 × 90 mm	Each	28	IPC
115	Drape, surgical, woven, 100 × 150 cm	Each	168	IPC
116	Test pregnancy, strip, temperature stable	Each	3,250	Laboratory
117	Test urinary protein, strip	Each	15,200	Laboratory
118	Bag (envelope), plastic, for drugs, 10 × 15 cm	Each	193,800	Other
119	Sling, for use with infant scale	Each	380	Other
120	Kerosene storm lamp + extra socks	Each	76	Other
121	Soap, hand, bar, 110 g, wrapped	Each	2,280	Other
122	Indicator, TST control, spot, adhesive	Each	22,800	Other
123	Gel, ultrasound, bottle, min. 250ml	Bottle	8,000	Other
124	LIDOCAINE HCl 2% STERILE GEL 11 GM	Tube	7,272	Other

Notes:

- *UNFPA preserves the right to adjust (increase/decrease) quantities without incurring any additional charges.*

Bid Submission:

If you are interested in submitting a bid for these items, kindly fill in the attached submission forms and send to the secure email address not later than **01st December 2024 at 14:00 Palestine local time**

Please ensure to mark your email with the ITB reference number and the words “Do not open before {01 Dec. 2024 at 14:00 Palestine local time}”.

Secure email address for bid submission: palestine.proc@unfpa.org

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

Questions or Clarifications related to the Bid:

Any questions or clarifications relating to the Bid process and/or to the attached documents shall be sent to: **Nibal Qundos** and **Razan Khalilieh** at emails: gundos@unfpa.org / khalilieh@unfpa.org no later than **18th November 2024**

Note: Do not submit or cc your bid/proposal submission to the contact person's email address mentioned in this section!

Documents to be submitted with the bid:

DOCUMENT CHECKLIST - Please remember to submit the following documents:

Note: Bidders are requested to name files clearly and organize documents by category to streamline the review process.

No.	DOCUMENT NAME	<input type="checkbox"/>
1	Annex 1 - Bid Submission Form - Completed and Signed	<input type="checkbox"/>
2	Annex 2 - Bidders Identification Form - Completed	<input type="checkbox"/>
3	Annex 3 - Product Item Overview Form - Completed	<input type="checkbox"/>
4	Annex 5 - Price Schedule Form - Completed and Signed	<input type="checkbox"/>

No.	DOCUMENT NAME	<input type="checkbox"/>
5	A statement whether any import or export licenses are required in respect of the goods to be purchased including any restrictions on the country of origin, use/dual use nature of goods or services, including and disposition to end users;	<input type="checkbox"/>
6	<ul style="list-style-type: none"> - Latest Business Registration Certificate; - Latest Internal Revenue Certificate / Tax Clearance; - Manufacturer's Authorization of the Company as a Sales Agent (if Bidder is not the manufacturer); 	<input type="checkbox"/>
7	Certificate of Exclusive Distributorship in the country (if applicable, and if Bidder is not the manufacturer);	<input type="checkbox"/>
8	Complete documentation, information and declaration of any goods classified or may be classified as "Dangerous Goods"	<input type="checkbox"/>
9	Patent Registration Certificates (if any of technologies submitted in the quotation is patented by the Supplier)	<input type="checkbox"/>
10	Written Self-Declaration of not being included in the UN Security Council 1267/1989 list, UN Procurement Division List or other UN Ineligibility List	<input type="checkbox"/>
11	Complete Technical bid submission, including detailed Technical specifications, product catalogue, technical data sheets and schematic drawings (when applicable) to demonstrate that specification and quality of the products are in line with the requirements listed in the bidding document.	<input type="checkbox"/>
12	<p>Quality Assurance Documents to be submitted:</p> <p>Below are Guidelines describing the minimum documentation required to be submitted by the bidders and can be found in the tables below as per each product group: Pharmaceuticals, medical devices and IVDs.</p> <p>All certificates and approvals must be valid at the time of bid submission.</p>	

No.	DOCUMENT NAME	<input type="checkbox"/>
12.1	<p>Documents to be submitted for Pharmaceuticals:</p> <ul style="list-style-type: none"> ● Annex 4.1 - Fast Track Procurement Questionnaire for Pharmaceuticals - duly completed by bidder and signed for each of the items included in the submission. ● Evidence that the product is registered in the country of intended use ● Evidence that the product is included in the Country National list of essential medicines. ● GMP certificate for Finished Pharmaceutical Product (FPP) manufacturer ● Certificate of analysis for at least one recently released batch. ● Package insert if applicable and patient information leaflet (PIL) (IN ENGLISH AND ARABIC) ● Photos of the finished pharmaceutical product and labeling. ● Signed declaration that the product to be supplied meets the locally approved specifications and is manufactured under cGMP 	<input type="checkbox"/>
12.2	<p>Documents to be submitted for Medical Devices:</p> <ul style="list-style-type: none"> ● Annex 4.2 - Fast Track Procurement Questionnaire for Medical Devices - duly completed by bidder and signed for each of the items included in the submission. ● Minimum documentation as per below table corresponding to classification of Medical Devices (ref. European Commission, MEDDEV 93/42/EEC). ● Photos of the medical devices product and packaging (preferably in a format where the dimension and features can be visible). 	<input type="checkbox"/>

No.	DOCUMENT NAME	<input type="checkbox"/>
Product class (as per EC MEDDEV)	Minimum documentation required for Medical Devices	
class I (non-measuring, non-sterile and/or non-reusable surgical instrument, rsi)	<ol style="list-style-type: none">1. Copy of ISO 13485 or ISO 9001 QMS certificate.2. A signed and dated Declaration of Conformity (DoC) according to ISO 17050 stating compliance to the relevant ISO standards and directives (e.g. CE self-declaration 93/42/EEC), and which has a reference to the offered product.	
class I measuring class I sterile class I rsi class IIa	<ol style="list-style-type: none">1. EC certificate (referencing the name/number of the notifying body), and/or 510k (FDA clearance), and/or approval letter or certificate from national regulatory body.2. A signed and dated DoC according to ISO 17050 stating compliance to critical ISO standards (e.g. for sterilization, ISO 13485 QMS) and directives, and which has a reference to the offered product. Note: If a sterilization activity is subcontracted to a third party, ISO 13485 QMS compliance is also required from the subcontracting company.	
class IIb class III	<ol style="list-style-type: none">1. EC certificate (referencing the name/number of the notifying body) with an additional copy of EC Design Examination certificate, and/or 510k/PMA FDA clearance, and/or approval letter or certificate from national regulatory body.2. A signed and dated DoC according to ISO 17050 stating compliance to critical ISO standards (e.g. ISO 13485 QMS) and directives, and which has a reference to the offered product. Proof of compliance to ISO standards in a form of copies of certificates shall be submitted if available.	

Examples of products in each of the Medical Device EC MEDDEV class:

- **Class I** (non-measuring, non-sterile and/or non-reusable surgical instrument) Aprons, bags, baskets, bowls, etc. (largest item class group in UNFPA procurement catalog).
- **Class I** (measuring, sterile and/or reusable surgical instrument) Thermometers, scales, catheters, cytobrushes, sterile surgical and gynecological instruments, sterile gloves and supplies, reusable surgical and gynecological instruments, etc.
- **Class IIa:** Cannulas, needles, blades, pumps (manual, electrical), resuscitators, etc. (Many of the class IIa products are also sterile products.)
- **Class IIb and III:** Anaesthesia machines, cryosurgical units, sutures, baby warmers and incubators, infusion pumps etc.

No.	DOCUMENT NAME	<input type="checkbox"/>
12.3	<p>Documents to be submitted for In Vitro Diagnostics (IVD):</p> <ul style="list-style-type: none"> ● Annex 4.3 - Fast Track Procurement Questionnaire for IVD products - duly completed by bidder and signed for each of the items included in the submission. ● Evidence that the product is registered in the country of intended use. ● Evidence that the product is included in the Country National list of essential medicines. <p>Minimum documentation:</p> <ul style="list-style-type: none"> ● ISO 13485 QMS certificates, and GMP certificate if available. ● A signed and dated DoC according to ISO 17050 stating compliance to critical ISO standards and directives, and which has reference to the offered product. ● Copy of EC certificate 98/79/EC, and/or 510k/PMA clearance (FDA), and/or other Stringent Regulatory Agency certificates or approval letters. ● Certificate of analysis for at least recently released batch. ● Proof of WHO prequalification (if not prequalified, see list of other options below). ● Photos of the finished IVD product and labelling. <p>If the IVD product is not WHO prequalified or mentioned on WHO webpage as such, the product* must have undergone:</p> <ol style="list-style-type: none"> 1) a WHO Emergency Use Evaluation and Listing of IVDs (EUAL), or 2) an US FDA Emergency Use of Medical Products and Related Authorities (EUA), or 3) an approval process from Stringent Regulatory Authority (SRA) designated by Global Harmonization Task Force (GHFT) Competent Authority. <p>* Any product registered for “Research Use Only” or “For Export Only” is not acceptable, unless specifically authorised in writing by UNFPA.</p>	<input type="checkbox"/>

Partial Bids:

Partial bids are **allowed** under this ITB. Note: Partial bids mean that the bidder does not have to quote for all LOTs to submit a complete bid. **However, within each LOT, at least 80% of the items must be offered.**

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.

UNFPA reserves the right to select and accept a part or parts of any Bid submitted.

Pre-Bid Meeting:

A pre-bid meeting will be held on **14th November 2024** via Google Meet. This meeting aims to provide potential bidders with an opportunity to seek clarification on the tender requirements, ask questions, and discuss the submission process. Attendance is strongly encouraged to ensure a comprehensive understanding of the tender specifications

Google Meet info:***RH Pharmaceuticals & Medical Supplies (UNFPA-PAL-ITB-2024-012)***

Thursday, November 14, 2024 at 13:00 – 14:00 / Time zone: Asia/Hebron

Video call link: <https://meet.google.com/fbw-guvr-onx>

Or dial: (US) +1 307-312-0340 PIN: 881 860 490#

More phone numbers: <https://tel.meet/fbw-guvr-onx?pin=8820623662631>

INCOTERMS 2020 & Delivery Destination:**Delivery Options are as follows:**

- | | |
|----|---------------------------------|
| 1. | DAP Al Arish, Egypt / Port Said |
| 2. | DAP Cairo Airport |
| 3. | DAP Ashdod Port |
| 4. | DAP Amman warehouse, Jordan |
| 5. | DAP Kerem Shalom Crossing |
| 6. | DDP Ramallah, Palestine |

For deliveries to **Gaza**, the assigned delivery end point will be selected from Options 1–5, as determined by logistical requirements.

For deliveries to the **West Bank**, the delivery end point will be restricted to Option 6.

Currency:

Prices shall be quoted in **USD**

- For Bidders with Palestinian Registration: **Prices must be EXCLUSIVE OF VAT. (UNFPA will provide Tax Exemption to the Supplier)**
- For International Bidders: **Prices must be INCLUSIVE OF VAT/TAX. (UNFPA will **NOT** provide Tax Exemption to the Supplier)**

Validity of Bid:

The prices of the bid shall be valid for **180 days** after the closing date of bid submission as specified by UNFPA. A bid valid for a shorter period shall be rejected by UNFPA.

Delivery Time:

Bidders are requested to fill the delivery lead time in “Annex 5 - Price Schedule Form”.

Technically accepted offers will be evaluated on unit cost and delivery lead times, with preference given to offers that combine competitive pricing and lead times.

Evaluation of Bids:

UNFPA shall compare all substantially responsive bids to determine the lowest priced substantially responsive bid considering the delivery lead time.

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.
- d. Bidder’s full acceptance of the UNFPA General Terms and Conditions.


Contract Award:

UNFPA shall award multiple Long-Term Agreements (LTAs) to the lowest priced bidder(s) for each designated delivery destination, provided the bid has been determined to be substantially responsive with the bidding documents. Note: The technically acceptable lowest priced offer will be evaluated Item by Item per each delivery destination.

Note: Current UNFPA supplier policies apply to this solicitation and can be found at: <http://www.unfpa.org/suppliers>.

Name: Farah Altarifi

Title: Humanitarian Supplies Logistics Specialist Team Lead
Palestine Country Office

DocuSigned by:

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Attachments:

- **Annex 1 - Bid Submission Form**
- **Annex 2 - Bidders Identification Form**
- **Annex 3 - Product Item Overview Form**
- **Annex 4.1 - Fast Track Procurement Questionnaire for Pharmaceuticals (Attached)**
- **Annex 4.2 - Fast Track Procurement Questionnaire for Medical Devices (Attached)**
- **Annex 4.3 - Fast Track Procurement Questionnaire for IVD Products (Attached)**
- **Annex 5 - Price Schedule Form (Attached)**
- **Annex 6 – Technical Specification**

Annex 1 - Bid Submission Form**Invitation to Bid (ITB) No. UNFPA-PAL-ITB-2024-012**

Name of Bidder:	
Contact Person:	
Title:	
Email Address:	
Telephone Number:	
Date of Bid:	
Bid No:	
Currency of Bid price:	
Delivery time <i>(days from receipt of order till dispatch):</i>	
Expiration of Validity of Bid/Proposal <i>(The bid shall be valid for a period of at least 180 days after the Closing date.):</i>	

Vendor's Comments:

I hereby certify that this company, which I am duly authorized to sign for, accepts the General Terms and Conditions of UNFPA <http://www.unfpa.org/resources/unfpa-general-conditions-contract> **and we will abide by this bid/proposal until it expires.**

We undertake, if our bid/proposal is accepted, to commence and complete delivery of all items in the contract within the time frame stipulated.

We understand that you are not bound to accept any bid you may receive and that a bidding contract would result only after final negotiations are concluded on the basis of the technical and price bids proposed.

Name and title

Date and Place

Annex 2 - Bidders Identification Form
Invitation to Bid (ITB) No. UNFPA-PAL-ITB-2024-012

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. Previous Experience and Similar main projects

Project	Country/Region	Type of Commodity	Project value in USD
1.			
2.			
3.			

6. 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

Annex 3 - Product Item Overview Form**ITB No. UNFPA-PAL-ITB-2024-012****Product's adherence to specifications**

The product supplied by manufacturers (and Suppliers, if different from the manufacturer) shall conform with the UNFPA technical specifications or be similar. Bidders are to state clearly in the below table, whether each criteria of the technical specifications matches or not and clearly state the Bidder's specifications in the below field for each item. The full specifications must be provided.

The bidder SHOULD NOT copy and paste UNFPA's specifications.

Note: For any items not included in your bid, please leave the relevant fields blank or enter "N/A" (Not Applicable) to indicate no bid for that item.

LOT #1 – Pharmaceuticals			
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	Povidone iodine 10% solution for cutaneous use, 500ml bottle		
2	Ferrous III as polymaltose complex (50mg/ml elemental iron)15ml drops.		
3	Ibuprofen 400mg tablet		
4	Metronidazole 250mg tablet		
5	anti-D (RhO) immunoglobulin 300mcg (winrho SDF)		

Annex 3 - Product Item Overview Form**ITB No. UNFPA-PAL-ITB-2024-012****LOT #1 – Pharmaceuticals**

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)
6	Iron 60mg+Folic Acid 0.4 Tablets Ferrous fumarate /Folic acid coated 185mg (60mg/0.4mg)		
7	Paracetamol 500mg tablets		
8	Calcium carbonate 600 mg Chewable Tablet		
9	Hydralazine 20mg I.M. I.V. 2 ml Hydralazine hydrochloride 20mg/2ml powder for injection in 2ml ampoule		
10	Methylergotamine 0.2 mg		
11	Dexamethasone sodium phosphate 4mg base/ml in 1ml ampoule		
12	Multivitamin coated tablets for pregnant women Minimum required ingredients: Folic Acid, Iron, Calcium, Vitamin D, Iodine,		

Annex 3 - Product Item Overview Form

ITB No. UNFPA-PAL-ITB-2024-012

LOT #1 – Pharmaceuticals

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)
	Vitamin B12, Vitamin C, Omega-3 Fatty Acids, and Zinc.		
13	Alprostadil (PGE1) 0.5 mg / ml , 1 ml		
14	Enoxaparin prefilled syringes 60 mg/ml (Clexane) Enoxaparin 60mg/0.6ml injection, pre-filled syringe		
15	Vitamin K1, injection, 1 mg/ml, 1-ml vial Vitamin K1 (phytomenadione) 1mg/ml injection		
16	Tranexamic acid, injection, 100 mg/ml, 10-ml ampoule		
17	Ergometrine maleate 0.2mg base/ml injection in 1ml ampoule		
18	Heparin sodium 5000 IU/ml 5 ml. Specifications: Heparin 5000IU/ml inj, 5ml vial/PAC-10		

Annex 3 - Product Item Overview Form**ITB No. UNFPA-PAL-ITB-2024-012****LOT #1 – Pharmaceuticals**

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)
19	Nifedipine (Oral Route) 30 mg, tab		
20	Nifedipine (Oral Route) 60 mg, tab		
21	Azithromycin 250 mg, tablet		
22	Azithromycin dihydrate 200 mg base/5-ml suspension, 15-ml bottle Product Specifications: Azithromycin pdr/or s 200mg/5ml/BOT-15ml		
23	Cefixime 200 mg, tablet		
24	Cefixime trihydrate 100 mg/5-ml powder for oral suspension, 30 ml		
25	Lamivudine 300 mg + tenofovir 300 mg, tablet		

Annex 3 - Product Item Overview Form

ITB No. UNFPA-PAL-ITB-2024-012

LOT #1 – Pharmaceuticals			
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)
	Lamivudine 300mg + Tenofovir Disoproxil Fumarate 300mg Tablets		
26	Atazanavir (ATV) 300 mg + ritonavir (r) 100 mg, tablet		
27	Lamivudine 30 mg + zidovudine 60 mg, tablet		
28	Lopinavir (LPV) 200 mg + ritonavir (r) 50 mg, tablet		
29	Lopinavir (LPV) 100 mg + ritonavir (r) 25 mg, tablet		
30	Benzathine benzylpenicillin 1.44 g (2.4 MIU), 5-ml vial		
31	Benzathine benzylpenicillin 900 mg (1.2 MIU), 5-ml vial		
32	Water for injection, sterile, 10-ml ampoule		

Annex 3 - Product Item Overview Form**ITB No. UNFPA-PAL-ITB-2024-012****LOT #1 – Pharmaceuticals**

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)
	Water for injection in 10ml plastic ampoule		
33	Clotrimazole 500 mg + applicator, vaginal tablet		
34	Ampicillin sodium 500 mg, powder for injection in vial Ampicillin as sodium salt powder for injection 500mg vial		
35	Gentamicin sulfate 40-mg base/ml for injection in 2-ml ampoule		
36	Clindamycin, injection, 600mg (as phosphate)/4-ml ampoule Clindamycin solution 150mg/ml (as phosphate) packed in 4ml ampoule		
37	Amoxicillin, powder for oral suspension, 125 mg/5 ml, 100-ml bottle Amoxicillin powder for oral suspension		

Annex 3 - Product Item Overview Form**ITB No. UNFPA-PAL-ITB-2024-012****LOT #1 – Pharmaceuticals**

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)
	125mg/5ml 100 ml bottle.Child resistant packaging and closure plastic bottle.		
38	Misoprostol 200 µg, tablet		
39	Ferrous fumarate 185 mg (60 mg iron)/folic acid 0.4 mg, tablet		
40	Tetracycline hydrochloride 1%, eye ointment, 5-g tube		
41	Lidocaine hydrochloride 1%, 20-ml ampoule USP or BP or equivalent		
42	Oxytocin 10 IU/ml for injection in 1-ml ampoule (keep cold: 2–8°C)		
43	Sodium lactate (Ringer's lactate), IV infusion, 1 litre + giving set Sodium lactate compound solution (Ringers lactate) solution for infusion 1000ml bottle with an infusion-giving set		

Annex 3 - Product Item Overview Form**ITB No. UNFPA-PAL-ITB-2024-012****LOT #1 – Pharmaceuticals**

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)
	sterile single use. Plastic bottle compliant with USP. Cap - E		
44	Glucose 5%, isotonic, 1 litre + infusion set, sterile, single use		
45	Magnesium sulfate 500 mg/ml for injection in 10-ml ampoule		
46	Hydralazine hydrochloride 20 mg/2 ml for injection in 2-ml ampoule Hydralazine hydrochloride 20mg/2ml powder for injection in 2ml ampoule		
47	Calcium gluconate 100 mg base/ml for injection in 10-ml ampoule		
48	Vitamin K, injection, 2 mg/0.2-ml vial		
49	Sodium chloride 0.9%, injection, 10-ml ampoule		

Annex 3 - Product Item Overview Form**ITB No. UNFPA-PAL-ITB-2024-012****LOT #1 – Pharmaceuticals**

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)
50	Chlorhexidine gluconate 4% solution (Hibiscrub), 500-ml bottle		
51	Povidone-iodine 10% solution for cutaneous use, 1-litre bottle		
52	Cloxacillin, powder for solution (IV/IM), 500-mg vial		
53	Glucose 10%, injection, 10-ml ampoule		
54	Epinephrine (adrenaline), injection, 1 mg/ml, 1-ml ampoule		
55	Bupivacaine hydrochloride (as anhydrous) 0.5%, intrathecal injection, 5 mg/ml, 10-ml ampoule		
56	Atropine sulfate 1 mg/ml for injection in 1-ml ampoule		

Annex 3 - Product Item Overview Form**ITB No. UNFPA-PAL-ITB-2024-012****LOT #1 – Pharmaceuticals**

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)
57	Ephedrine hydrochloride, 30 mg/ml for injection in 1-ml ampoule		
58	Ketamine hydrochloride 50 mg base/ml for injection in 10-ml vial		
59	INSULIN ASPART 100 IU/ML 3 ML PREFILLED PENS		
60	METFORMIN 850MG TAB		
61	AMPICILLIN 1 G VIAL Ampicillin sodium 1000mg (1g) powder for solution for injection in vial		
62	DEXT.50% SOLN 500ML		
63	METHOTREXATE SOD. 50 MG VIAL Methotrexate 50mg solution for injection, vial		

Annex 3 - Product Item Overview Form**ITB No. UNFPA-PAL-ITB-2024-012****LOT #1 – Pharmaceuticals**

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)
64	Levothyroxine 100mcg tablets		
65	fluconazole 2mg/ml 50 ml vial		
66	RAPID ACTING INSULINE ANALOGUE100 U/ML 3ML PFP		
67	ASPIRIN 100MG TAB		
68	FERROUS SLF160MG (50 mg iron)+FOLIC ACID 400MCG TAB		
69	PREDNISOLONE 20MG TAB		
70	OMEPRazole 20MG TAB OR CAP		
71	Levothyroxine 50mcg tablets		

Annex 3 - Product Item Overview Form**ITB No. UNFPA-PAL-ITB-2024-012****Product's adherence to specifications**

The product supplied by manufacturers (and Suppliers, if different from the manufacturer) shall conform with the UNFPA technical specifications or be similar. Bidders are to state clearly in the below table, whether each criteria of the technical specifications matches or not and clearly state the Bidder's specifications in the below field for each item. The full specifications must be provided.

The bidder SHOULD NOT copy and paste UNFPA's specifications.

[Please refer to Annex 6 for detailed description. Click [HERE](#) to navigate directly]

LOT #2, 3 & 4 – Medical Supplies [Click HERE to navigate directly]				
Item No.	Description and Minimum / Mandatory Specifications	Category	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	Gloves, surgical, size 7,5, powder-free, sterile, single use	Disposables		
2	Gloves, surgical, size 8, powder-free, sterile, single use,	Disposables		
3	Gloves, exam, latex, non-sterile, single use, (large size)	Disposables		
4	Gloves, exam, latex, non-sterile, , single use, (medium size)	Disposables		
5	Operation room face mask disposable, made of non tranmitant fabric material, not paper	Disposables		
6	Disposable medical gown	Disposables		
7	Umbilical Cord Clamp	Disposables		

Annex 3 - Product Item Overview Form**ITB No. UNFPA-PAL-ITB-2024-012****LOT #2, 3 & 4 – Medical Supplies** [Click [HERE](#) to navigate directly]

Item No.	Description and Minimum / Mandatory Specifications	Category	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)
8	Vaginal Speculum (Large) Plastic	Disposables		
9	Vaginal Speculum (Medium) Plastic	Disposables		
10	Vaginal Speculum (Small) Plastic	Disposables		
11	Vaginal Speculum (Large)	Surg. Instrument		
12	Vaginal Speculum (Medium)	Surg. Instrument		
13	Vaginal Speculum (Small)	Surg. Instrument		
14	Bed sheet, cotton or cotton blend (majority cotton), single-bed, 220 x 110 cm	Bedding		
15	Disposable Waterproof Non-Woven Fabric Bed Sheet for Patients, Hospital Bed, Adults (Standard size)	Bedding		
16	Hand Sanitizer, Alcohol 70-80%, 0.5 Ltr	IPC		

Annex 3 - Product Item Overview Form

ITB No. UNFPA-PAL-ITB-2024-012

LOT #2, 3 & 4 – Medical Supplies [Click [HERE](#) to navigate directly]

Item No.	Description and Minimum / Mandatory Specifications	Category	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)
17	Sharps container, 3-5 L, cardboard	IPC		
18	HemoCue Hb 201 Microcuvettes, Strip (<i>IVD Product - See required documentation</i>)	Laboratory		
19	HemoCue Hb 301 Microcuvettes(<i>IVD Product - See required documentation</i>)	Laboratory		
20	Placenta Pan / basin, stainless stell, 600-800 CC, with cover	Instruments		
21	Ambu Bag, neonatal, 200–320 mL. Intake valve with optional nipple for O2 tubing: polycarbonate/ polysulfone or other material fulfilling the ISO 10651-4 or equivalent.	Instruments		
22	Paper CTG, Thermal, Z-fold P4,	Medical Stationary		
23	Autoclave Tape-Sterilization Tape (3/4" Wide) 50m	Medical Stationary		
24	Syringe, Luer, 2 ml, sterile, single use	Disposables		
25	Needle, Luer, 21G, sterile, single use	Disposables		

Annex 3 - Product Item Overview Form**ITB No. UNFPA-PAL-ITB-2024-012****LOT #2, 3 & 4 – Medical Supplies** [Click [HERE](#) to navigate directly]

Item No.	Description and Minimum / Mandatory Specifications	Category	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)
26	Cotton wool, 500 g, roll, non-sterile	Disposables		
27	Syringe,disp,5ml,ster/BOX-100	Disposables		
28	Tourniquet, latex rubber, 75 cm	Disposables		
29	Clamp, umbilical, 5.2 cm, sterile, single use	Disposables		
30	Cannula, IV short, 20G, sterile, single use	Disposables		
31	Syringe,disp,10ml,ster/BOX-100	Disposables		
32	Syringe,disp,1ml,ster/BOX-100	Disposables		
33	Needle, Luer, 25G, sterile, single use	Disposables		
34	Syringe, feeding, catheter tip, 50 ml, sterile, single use	Disposables		
35	Gloves, surgical, size 7, powder free, sterile, single use	Disposables		

Annex 3 - Product Item Overview Form

ITB No. UNFPA-PAL-ITB-2024-012

LOT #2, 3 & 4 – Medical Supplies [Click [HERE](#) to navigate directly]

Item No.	Description and Minimum / Mandatory Specifications	Category	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)
36	Gloves, gynaecological, medium, powder free, sterile	Disposables		
37	Suture, absorbable, DEC3(2-0), 3/8, 30 mm, round, sterile	Disposables		
38	Extractor, mucus, 20 ml, sterile, single use	Disposables		
39	Tube, suction, CH10, 50-cm long, conical tip, sterile	Disposables		
40	Tube, suction, CH14, 50-cm long, conical tip, sterile	Disposables		
41	Catheter, urethral, CH12, sterile	Disposables		
42	Gauze, compress, 10 × 10 cm, sterile	Disposables		
43	Tape, adhesive, zinc oxide, 2.5 cm × 5 m	Disposables		
44	Suture, absorbable, DEC4(1), 3/8, 36 mm, triangular, sterile	Disposables		
45	Suture, absorbable, DEC3(2-0), 1/2, 30 mm, round, sterile	Disposables		

Annex 3 - Product Item Overview Form**ITB No. UNFPA-PAL-ITB-2024-012****LOT #2, 3 & 4 – Medical Supplies** [Click [HERE](#) to navigate directly]

Item No.	Description and Minimum / Mandatory Specifications	Category	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)
46	Suture, absorbable, DEC3(2-0), 3/8, 50 mm, round, sterile	Disposables		
47	Syringe, 0.5 ml, permanently attached needle, sterile, single use	Disposables		
48	Disinfectant tablet for water containing 1.67 g of sodium dichloroisocyanurate (NaDCC)	Disposables		
49	Cannula, IV short, 18G, sterile, single use	Disposables		
50	Syringe, Luer lock, 20 ml, sterile, single use	Disposables		
51	Needle, Luer, 23G, sterile, single use	Disposables		
52	Needle, scalp vein, butterfly, 25G, sterile, single use	Disposables		
53	Suture, non-absorbable, DEC3(2-0), 3/8, triangular, 30 mm, sterile	Disposables		
54	Catheter, urethral, Foley, CH14, sterile	Disposables		
55	Bag, urine, collecting, 2 litres	Disposables		

Annex 3 - Product Item Overview Form**ITB No. UNFPA-PAL-ITB-2024-012****LOT #2, 3 & 4 – Medical Supplies** [Click [HERE](#) to navigate directly]

Item No.	Description and Minimum / Mandatory Specifications	Category	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)
56	Needle, spinal, 22G, sterile, single use	Disposables		
57	Tape, adhesive, zinc oxide, perforated, 10 cm × 5 m	Disposables		
58	Blade, scalpel, sterile, single use, no. 22	Disposables		
59	Basin, kidney, stainless steel, 825 ml	Instruments		
60	Tray, instruments, stainless steel, 22.5 × 12.5 × 5 cm	Instruments		
61	Scissors, Mayo, 14 cm, curved, blunt/blunt	Instruments		
62	Scissors, gynaecological, 20 cm, curved, blunt/blunt	Instruments		
63	Timer, 60 minutes, mechanical	Instruments		
64	Drum, sterilizing, diameter 165 mm	Instruments		
65	Drum, sterilizing, diameter 260 mm	Instruments		

Annex 3 - Product Item Overview Form**ITB No. UNFPA-PAL-ITB-2024-012****LOT #2, 3 & 4 – Medical Supplies** [Click [HERE](#) to navigate directly]

Item No.	Description and Minimum / Mandatory Specifications	Category	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)
66	Drum, sterilizing, diameter 290 mm	Instruments		
67	Flashlight, frontal, LED, battery operated, including batteries	Instruments		
68	Scissors, Mayo, 17 cm, curved, blunt/blunt	Instruments		
69	Needle holder, Mayo-Hegar, 18 cm, straight	Instruments		
70	Retractor, vaginal, Doyen, 8.5 × 4.5 cm	Instruments		
71	Speculum, vaginal, Graves, 75 × 20 mm	Instruments		
72	Speculum, vaginal, Graves, 95 × 35 mm	Instruments		
73	Speculum, vaginal, Graves, 115 × 35 mm	Instruments		
74	Forceps, dressing, Cheron, 25 cm	Instruments		
75	Tray, instruments, stainless steel, 32 × 20 × 8 cm, with cover	Instruments		

Annex 3 - Product Item Overview Form**ITB No. UNFPA-PAL-ITB-2024-012****LOT #2, 3 & 4 – Medical Supplies** [Click [HERE](#) to navigate directly]

Item No.	Description and Minimum / Mandatory Specifications	Category	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)
76	Clamp, towel, Backhaus, 120 mm	Instruments		
77	Forceps, artery, Kelly, 14 cm, curved	Instruments		
78	Forceps, artery, Halsted-Mosquito, 12.5 cm, curved	Instruments		
79	Forceps, artery, Kocher, 14 cm, straight	Instruments		
80	Forceps, artery, Rochester-Pean, 20 cm, curved	Instruments		
81	Forceps, artery, Rochester-Pean, 24 cm, curved	Instruments		
82	Forceps, artery, Mixer, 23 cm	Instruments		
83	Forceps, dressing, standard, 145 mm, straight	Instruments		
84	Forceps, dressing, standard, 250 mm, straight	Instruments		
85	Forceps, intestinal clamp, Doyen, 23 cm, curved	Instruments		

Annex 3 - Product Item Overview Form**ITB No. UNFPA-PAL-ITB-2024-012****LOT #2, 3 & 4 – Medical Supplies** [Click [HERE](#) to navigate directly]

Item No.	Description and Minimum / Mandatory Specifications	Category	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)
86	Forceps, uterine, Phaneuf, 21.5 cm, curved	Instruments		
87	Forceps, uterine, Duplay, 28 cm, curved	Instruments		
88	Forceps, tissue, Allis, 4 × 5 teeth, 15 cm	Instruments		
89	Forceps, tissue, Babcock, 20 cm	Instruments		
90	Forceps, tissue, Duval, 23 cm	Instruments		
91	Forceps, tissue, standard, 145 mm, straight	Instruments		
92	Forceps, tissue, standard, 250 mm, straight	Instruments		
93	Bowl, stainless steel, 500 ml	Instruments		
94	Retractor, abdominal, Collin, three blades	Instruments		
95	Retractor, abdominal, Balfour, three blades	Instruments		

Annex 3 - Product Item Overview Form**ITB No. UNFPA-PAL-ITB-2024-012****LOT #2, 3 & 4 – Medical Supplies** [Click [HERE](#) to navigate directly]

Item No.	Description and Minimum / Mandatory Specifications	Category	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)
96	Retractor, double-ended, Farabeuf, 15 cm, pair	Instruments		
97	Scalpel handle no. 4, blade holder, 13 cm	Instruments		
98	Scissors, Metzenbaum/Nelson, 18 cm, curved, blunt/blunt	Instruments		
99	Scissors, Metzenbaum/Nelson, 23 cm, curved, blunt/blunt	Instruments		
100	Scissors, Mayo, 23 cm, curved, blunt/blunt	Instruments		
101	Spatula, Ribbon retractor, malleable, 27 × 250 mm	Instruments		
102	Tube, suction, Yankauer, 28 cm	Instruments		
103	Cranioclast, Braun, 420 mm	Instruments		
104	Perforator, Smellie, 25 cm	Instruments		
105	Hook, decapitation, Braun, 31 cm	Instruments		

Annex 3 - Product Item Overview Form**ITB No. UNFPA-PAL-ITB-2024-012****LOT #2, 3 & 4 – Medical Supplies** [Click [HERE](#) to navigate directly]

Item No.	Description and Minimum / Mandatory Specifications	Category	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)
106	Bowl, stainless steel, 180 ml	Instruments		
107	Chlorhexidine digluconate 5% solution, 1-litre bottle	IPC		
108	Safety box, disposal of used syringes and needles, 5 litres	IPC		
109	Brush, hand, scrubbing, plastic	IPC		
110	Glasses, safety, regular size, disposable	IPC		
111	Apron, protection, plastic, reusable	IPC		
112	Draw sheet, plastic, 90 × 180 cm, reusable	IPC		
113	Bag, biohazard, yellow, 50 litres	IPC		
114	Basket, instruments, for sterilization, wired, 400 × 200 × 90 mm	IPC		
115	Drape, surgical, woven, 100 × 150 cm	IPC		

Annex 3 - Product Item Overview Form

ITB No. UNFPA-PAL-ITB-2024-012

LOT #2, 3 & 4 – Medical Supplies [Click [HERE](#) to navigate directly]

Item No.	Description and Minimum / Mandatory Specifications	Category	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)
116	Test pregnancy, strip, temperature stable	Laboratory		
117	Test urinary protein, strip	Laboratory		
118	Bag (envelope), plastic, for drugs, 10 × 15 cm	Other		
119	Sling, for use with infant scale	Other		
120	Kerosene storm lamp + extra socks	Other		
121	Soap, hand, bar, 110 g, wrapped	Other		
122	Indicator, TST control, spot, adhesive	Other		
123	Gel, ultrasound, bottle, min. 250ml	Other		
124	LIDOCAINE HCl 2% STERILE GEL 11 GM	Other		

Annex 4 - FTP Questionnaires
Invitation to Bid (ITB) No. UNFPA/PAL/ITB/2024/012
(Attached)

Bidders to complete and submit the below Questionnaire:

- Annex 4.1 - Fast Track Procurement Questionnaire for Pharmaceuticals (Attached)
- Annex 4.2 - Fast Track Procurement Questionnaire for Medical Devices (Attached)
- Annex 4.3 - Fast Track Procurement Questionnaire for IVD products (Attached)

*Note: The Questionnaire must be completed by the bidder and signed for **each of the items included in the submission.***

Annex 5 - Price Schedule Form
Invitation to Bid (ITB) No. UNFPA/PAL/ITB/2024/012

(Attached)

Note: The Price Schedule Form must be submitted in both Excel and PDF formats, signed and stamped by the bidder.

Annex 6 – Technical Specifications

ITB No. UNFPA/PAL/ITB/2024/012

LOT #1 – Pharmaceuticals			
Item No.	Item	UoM	Est. QTY
1	Povidone iodine 10% solution for cutaneous use, 500ml bottle	Bottle	400
2	Ferrous III as polymaltose complex (50mg/ml elemental iron)15ml drops.	Bottle	10,000
3	Ibuprofen 400mg tablet	Pack of 500	200
4	Metronidazole 250mg tablet	Pack of 1000	226
5	anti-D (RhO) immunoglobulin 300mcg (winrho SDF)	Vial	1,200
6	Iron 60mg+Folic Acid 0.4 Tablets Ferrous fumarate /Folic acid coated 185mg (60mg/0.4mg)	Pack of 100	30,000
7	Paracetamol 500mg tablets	Pack of 1000	1,225
8	Calcium carbonate 600 mg Chewable Tablet	Pack of 1000	952
9	Hydralazine 20mg I.M. I.V. 2 ml Hydralazine hydrochloride 20mg/2ml powder for injection in 2ml ampoule	Ampoule	1,200
10	Methylethylamphetamine 0.2 mg	Tab	4,000
11	Dexamethasone sodium phosphate 4mg base/ml in 1ml ampoule	Pack of 100	120
12	Multivitamin coated tablets for pregnant women Minimum required ingredients: Folic Acid, Iron, Calcium, Vitamin D, Iodine, Vitamin B12, Vitamin C, Omega-3 Fatty Acids, and Zinc.	Pack of 1000	1,000
13	Alprostadil (PGE1) 0.5 mg / ml , 1 ml	Ampoule	600
14	Enoxaparin prefilled syringes 60 mg/ml (Clexane) Enoxaparin 60mg/0.6ml injection, pre-filled syringe	Pre-filled syringe	4,000
15	Vitamin K1, injection, 1 mg/ml, 1-ml vial Vitamin K1 (phytomenadione) 1mg/ml injection	Ampoule	7,080
16	Tranexamic acid, injection, 100 mg/ml, 10-ml ampoule	Ampoule	3,280
17	Ergometrine maleate 0.2mg base/ml injection in 1ml ampoule	Ampoule	3,000
18	Heparin sodium 5000 IU/ml 5 ml. Specifications: Heparin 5000IU/ml inj, 5ml vial/PAC-10	Vial	8,000
19	Nifedipine (Oral Route) 30 mg, tab	Tab	2,000

Annex 6 – Technical Specifications

ITB No. UNFPA/PAL/ITB/2024/012

LOT #1 – Pharmaceuticals			
20	Nifedipine (Oral Route) 60 mg, tab	Tab	2,000
21	Azithromycin 250 mg, tablet	Pack of 1000	225
22	Azithromycin dihydrate 200 mg base/5-ml suspension, 15-ml bottle Product Specifications: Azithromycin pdr/or s 200mg/5ml/BOT-15ml	Bottle	2,730
23	Cefixime 200 mg, tablet	Tab	43,340
24	Cefixime trihydrate 100 mg/5-ml powder for oral suspension, 30 ml	Bottle	4,240
25	Lamivudine 300 mg + tenofovir 300 mg, tablet Lamivudine 300mg + Tenofovir Disoproxil Fumarate 300mg Tablets	Tab	16,200
26	Atazanavir (ATV) 300 mg + ritonavir (r) 100 mg, tablet	Tab	16,200
27	Lamivudine 30 mg + zidovudine 60 mg, tablet	Tab	25,920
28	Lopinavir (LPV) 200 mg + ritonavir (r) 50 mg, tablet	Tab	4,320
29	Lopinavir (LPV) 100 mg + ritonavir (r) 25 mg, tablet	Tab	6,480
30	Benzathine benzylpenicillin 1.44 g (2.4 MIU), 5-ml vial	Vial	5,720
31	Benzathine benzylpenicillin 900 mg (1.2 MIU), 5-ml vial	Vial	880
32	Water for injection, sterile, 10-ml ampoule Water for injection in 10ml plastic ampoule	Ampoule	40,800
33	Clotrimazole 500 mg + applicator, vaginal tablet	Tab	8,800
34	Ampicillin sodium 500 mg, powder for injection in vial Ampicillin as sodium salt powder for injection 500mg vial	Vial	26,400
35	Gentamicin sulfate 40-mg base/ml for injection in 2-ml ampoule	Ampoule	11,800
36	Clindamycin, injection, 600mg (as phosphate)/4-ml ampoule Clindamycin solution 150mg/ml (as phosphate) packed in 4ml ampoule	Ampoule	21,900
37	Amoxicillin, powder for oral suspension, 125 mg/5 ml, 100-ml bottle Amoxicillin powder for oral suspension 125mg/5ml 100 ml bottle.Child resistant packaging and closure plastic bottle.	Bottle	520
38	Misoprostol 200 µg, tablet	Tab	20,640
39	Ferrous fumarate 185 mg (60 mg iron)/folic acid 0.4 mg, tablet	Tab	380,000
40	Tetracycline hydrochloride 1%, eye ointment, 5-g tube	Tube	1,296
41	Lidocaine hydrochloride 1%, 20-ml ampoule USP or BP or equivalent	Ampoule	6,000
42	Oxytocin 10 IU/ml for injection in 1-ml ampoule (keep cold: 2–8°C)	Ampoule	21,600

Annex 6 – Technical Specifications

ITB No. UNFPA/PAL/ITB/2024/012

LOT #1 – Pharmaceuticals			
43	Sodium lactate (Ringer's lactate), IV infusion, 1 litre + giving set Sodium lactate compound solution (Ringers lactate) solution for infusion 1000ml bottle with an infusion-giving set sterile single use. Plastic bottle compliant with USP. Cap - E	Bottle	8,160
44	Glucose 5%, isotonic, 1 litre + infusion set, sterile, single use	Bottle	10,480
45	Magnesium sulfate 500 mg/ml for injection in 10-ml ampoule	Ampoule	3,560
46	Hydralazine hydrochloride 20 mg/2 ml for injection in 2-ml ampoule Hydralazine hydrochloride 20mg/2ml powder for injection in 2ml ampoule	Ampoule	4,728
47	Calcium gluconate 100 mg base/ml for injection in 10-ml ampoule	Ampoule	2,640
48	Vitamin K, injection, 2 mg/0.2-ml vial	Vial	3,800
49	Sodium chloride 0.9%, injection, 10-ml ampoule	Ampoule	8,880
50	Chlorhexidine gluconate 4% solution (Hibiscrub), 500-ml bottle	Bottle	748
51	Povidone-iodine 10% solution for cutaneous use, 1-litre bottle	Bottle	1,220
52	Cloxacillin, powder for solution (IV/IM), 500-mg vial	Vial	2,520
53	Glucose 10%, injection, 10-ml ampoule	Ampoule	3,360
54	Epinephrine (adrenaline), injection, 1 mg/ml, 1-ml ampoule	Ampoule	280
55	Bupivacaine hydrochloride (as anhydrous) 0.5%, intrathecal injection, 5 mg/ml, 10-ml ampoule	Ampoule	2,800
56	Atropine sulfate 1 mg/ml for injection in 1-ml ampoule	Ampoule	560
57	Ephedrine hydrochloride, 30 mg/ml for injection in 1-ml ampoule	Ampoule	4,200
58	Ketamine hydrochloride 50 mg base/ml for injection in 10-ml vial	Vial	1,400
59	INSULIN ASPART 100 IU/ML 3 ML PREFILLED PENS	Single	5,224
60	METFORMIN 850MG TAB	Th	4,556
61	AMPICILLIN 1 G VIAL Ampicillin sodium 1000mg (1g) powder for solution for injection in vial	Single	8,066
62	DEXT.50% SOLN 500ML	Single	1,060
63	METHOTREXATE SOD. 50 MG VIAL Methotrexate 50mg solution for injection, vial	Single	1,250
64	Levothyroxine 100mcg tablets	Th	322
65	fluconazole 2mg/ml 50 ml vial	Single	1,284
66	RAPID ACTING INSULINE ANALOGUE 100 U/ML 3ML PFP	Single	42,608

Annex 6 – Technical Specifications

ITB No. UNFPA/PAL/ITB/2024/012

LOT #1 – Pharmaceuticals			
67	ASPIRIN 100MG TAB	Th	3,008
68	FERROUS SLF160MG (50 mg iron)+FOLIC ACID 400MCG TAB	Th	1,196
69	PREDNISOLONE 20MG TAB	Th	74
70	OMEPRAZOLE 20MG TAB OR CAP	Th	1,454
71	Levothyroxine 50mcg tablets	Th	254

LOT #2, 3 and 4 – Medical Supplies

Item No.	Item	UoM	Quantity	Category
1	Gloves, surgical, size 7,5, powder-free, sterile, single use	Pair	30,000	Disposables
<p>Product description: Pair of surgical gloves anatomically shaped: 1 right-handed, 1 left-handed. Waterproof. Stretch-proof.</p> <p>Material: Natural latex. Powder-free.</p> <p>Size selected:</p> <p>Surgical gloves size: 7.5</p> <p>Total length: approximately 270mm</p> <p>Width: approximately 95 +/- 5mm</p> <p>Sterile and single use.</p> <p>Initial sterilisation method: Ethylene oxide gas or Gamma radiation.</p> <p>Instructions for use: Sterile single-use gloves used for surgical procedures to protect both patient and medical staff from cross-contamination. Surgical gloves are sterile and strictly SINGLE USE. This item must be ordered in sufficient quantity to encourage its use. The sizes have been chosen as being the most commonly used.</p> <p>Supplied with: Manufacturer's instructions for use.</p> <p>Packaging and labelling:</p> <ul style="list-style-type: none">Primary packaging: Unit of use. One (1) pair of gloves in an individual sterilised peel pack. Supplied with double packaging: one interior layer plus sterilised peel-pack. Packed in the interior layer: right and left hand with the sleeves reversed up to the thumb. Labelled with: size, right hand, left hand, and position of the sleeves.Secondary packaging: Protected unit. One (1) box of 50 pairs of gloves.				

LOT #2, 3 and 4 – Medical Supplies

Item No.	Item	UoM	Quantity	Category
<p>Symbols used according to ISO 15223.</p> <p>CE Mark with Notified Body number.</p> <p>Regulation & conformity requirements:</p> <p>CE mark conforming to Medical Device Directive 93/42/EEC.</p> <p>CE Certificate (class IIa).</p> <p>Classification: Class IIa - Medical Device Directive 93/42/EEC.</p> <p>Safety & product Standards:Must comply with the following standards:</p> <ul style="list-style-type: none">ISO 11607-1:2007 - Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems, and packaging systems.EN 455-1:2000 - Medical gloves for single use - Part 1: Requirements and testing for freedom from holes.EN 455-2:2009+A2:2013 - Medical gloves for single use - Requirements and testing for physical properties.EN 455-3:2006 - Medical gloves for single use - Part 3: Requirements and testing for biological evaluation.EN 455-4:2009 - Medical gloves for single use - Requirements and testing for shelf life determination.ISO 12243:2003 - Medical gloves made from natural rubber latex -- Determination of water-extractable protein using the modified Lowry method.				
2	Gloves, surgical, size 8, powder-free, sterile, single use,	Pair	46,120	Disposables
<p>Product description: Pair of surgical gloves anatomically shaped: 1 right-handed, 1 left-handed. Waterproof. Stretch-proof.</p> <p>Material: Natural latex. Powder-free.</p> <p>Size selected: Surgical gloves size: 8. Total length: approximately 270mm. Width: approximately 102 +/- 5mm.</p> <p>Sterile and single use. Initial sterilisation method: Ethylene oxide gas or Gamma radiation.</p> <p>Instructions for use: Sterile single-use gloves used for surgical procedures to protect both patient and medical staff from cross-contamination. Surgical gloves are sterile and strictly SINGLE USE. This item must be ordered in sufficient quantity to encourage its use. The sizes have been chosen as being the most commonly used.</p> <p>Supplied with: Manufacturer's instructions for use.</p> <p>Packaging and labelling:</p> <ul style="list-style-type: none">Primary packaging: Unit of use. One (1) pair of gloves in an individual sterilised peel pack. Supplied with double packaging: one interior layer plus sterilised peel-pack. Packed in the interior layer: right and left hand with the sleeves reversed up to the thumb. Labelled with: size, right hand, left hand, and position of the sleeves.Secondary packaging: Protected unit. One (1) box of 50 pairs of gloves. <p>Symbols used according to ISO 15223. CE Mark with Notified Body number.</p> <p>Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC. CE Certificate (class IIa).</p>				

Annex 6 – Technical Specifications**ITB No. UNFPA/PAL/ITB/2024/012****LOT #2, 3 and 4 – Medical Supplies**

Item No.	Item	UoM	Quantity	Category
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Classification: Class IIa - Medical Device Directive 93/42/EEC.

Safety & product Standards: Must comply with the following standards:

- ISO 11607-1:2007 - Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems, and packaging systems.
- EN 455-1:2000 - Medical gloves for single use - Part 1: Requirements and testing for freedom from holes.
- EN 455-2:2009+A2:2013 - Medical gloves for single use - Requirements and testing for physical properties.
- EN 455-3:2006 - Medical gloves for single use - Part 3: Requirements and testing for biological evaluation.
- EN 455-4:2009 - Medical gloves for single use - Requirements and testing for shelf life determination.
- ISO 12243:2003 - Medical gloves made from natural rubber latex -- Determination of water-extractable protein using the modified Lowry method.

3	Gloves, exam, latex, non-sterile, single use, (large size)	Pair	10,000	Disposables
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Product description: Glove for clinical examinations and routine clinical laboratory work. Contains 5 fingers, palm, and a sleeve. Fits either hand.

Material: Natural latex. Waterproof. Non-sterile. Single-use, disposable. Internally powdered glove for easy fitting. Powder used: maize starch.

Size: Large, Total length: minimum 240mm, Width: 110 mm +/- 10mm, Thickness: fingers minimum 0.12mm; palm minimum 0.1mm

Instructions for use: Used for multiple purposes in a wide range of laboratory services, from basic laboratories to reference centers.

Packaging and labelling: Unit presentation: 1 (one) Gloves exam latex large disp box/100

Symbols used according to ISO 15223.

CE Mark.

Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC. CE self-declaration. ISO 13845:2003 certified.

Classification: 93/42/EEC Class I – Self-declaration / CE certification.

Safety & product Standards: Must comply with the following standards:

- EN 455-1:2000 - Medical gloves for single use - Part 1: Requirements and testing for freedom from holes
- EN 455-2:2009+A2:2013 - Medical gloves for single use - Requirements and testing for physical properties
- EN 455-3:2006 - Medical gloves for single use - Part 3: Requirements and testing for biological evaluation
- EN 455-4:2009 - Medical gloves for single use - Requirements and testing for shelf life determination
- ISO 21171:2006 - Medical gloves - Determination of removable surface powder
- ISO 12243:2003 - Medical gloves made from natural rubber latex - Determination of water-extractable protein using the modified Lowry method

Annex 6 – Technical Specifications

ITB No. UNFPA/PAL/ITB/2024/012

LOT #2, 3 and 4 – Medical Supplies

Item No.	Item	UoM	Quantity	Category
4	Gloves, exam, latex, non-sterile, single use, (medium size)	Pair	47,400	Disposables
<p>Product description: Glove for clinical examinations and routine clinical laboratory work. Contains 5 fingers, palm, and a sleeve. Fits either hand.</p> <p>Material: Natural latex. Waterproof. Non-sterile. Single-use, disposable. Internally powdered glove for easy fitting. Powder used: maize starch.</p> <p>Size: Medium, Total length: minimum 240mm, Width: 95 mm +/- 10mm, Thickness: fingers minimum 0.12mm; palm minimum 0.1mm</p> <p>Instructions for use: Used for multiple purposes in a wide range of laboratory services, from basic laboratories to reference centers.</p> <p>Supplied with: Manufacturer's instructions for use.</p> <p>Packaging and labelling: Unit presentation: 1 (one) Gloves exam latex medium disp box/100</p> <p>Symbols used according to ISO 15223.</p> <p>CE Mark.</p> <p>Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC. CE self-declaration. ISO 13845:2003 certified.</p> <p>Classification: 93/42/EEC Class I – Self-declaration / CE certification.</p> <p>Safety & product Standards: Must comply with the following standards:</p> <ul style="list-style-type: none"> • EN 455-1:2000 - Medical gloves for single use - Part 1: Requirements and testing for freedom from holes • EN 455-2:2009+A2:2013 - Medical gloves for single use - Requirements and testing for physical properties • EN 455-3:2006 - Medical gloves for single use - Part 3: Requirements and testing for biological evaluation • EN 455-4:2009 - Medical gloves for single use - Requirements and testing for shelf life determination • ISO 21171:2006 - Medical gloves - Determination of removable surface powder • ISO 12243:2003 - Medical gloves made from natural rubber latex - Determination of water-extractable protein using the modified Lowry method 				
5	Operation room face mask disposable, made of non tranmitant fabric material, not paper Product Description: Mask,surgic,typellR,tiestrap,disp.pack50	Piece	60,000	Disposables
6	Disposable medical gown Product Description: Gown,surgic,sterile,nonwoven,STD,disp,L	Piece	60,000	Disposables
7	Umbilical Cord Clamp	Piece	5,000	Disposables
<p>Product description: Disposable sterile umbilical cord clamp, safe, effective, and easy to apply. Safe security lock with a click to indicate correct locking to protect against accidental re-opening after clamping. Grooves all along the length to prevent slip of the umbilical cord and to retain it in the same position. Finger grip to ensure safe and easy handling.</p> <p>Measurements: Approx. 52 mm</p> <p>Material: Plastic (polymer) medical grade. DEHP free. Single-use. Sterile.</p> <p>Supplied with: Manufacturer's instructions for use.</p> <p>Instructions for use: Disposable sterile umbilical cord clamp, safe, effective, and easy to apply, designed for clamping the umbilical cord soon after the birth. CE mark and reference number of notifying body.</p> <p>Packaging & Labelling: One (1) umbilical cord clamp in an individual sterilised peel pack. Symbols used according to ISO 15223 and EN 15986:2011. CE mark and reference number of notifying body.</p>				

Annex 6 – Technical Specifications

ITB No. UNFPA/PAL/ITB/2024/012

LOT #2, 3 and 4 – Medical Supplies

Item No.	Item	UoM	Quantity	Category
<p>Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC. CE certificate (class Is). ISO 13845:2003 certified.</p> <p>Classification: Class Is (I sterile) - Medical Device Directive 93/42/EEC.</p> <p>Safety & product Standards: Must comply with the following standards: ISO 13485: 2003, ISO 10993-1:2009, ISO 10993-7:2008</p> <p>Environmental requirements: PP, PE polymer, not PVC. PHT free.</p>				
8	Vaginal Speculum (Large) Plastic	Piece	1,500	Disposables
9	Vaginal Speculum (Medium) Plastic	Piece	1,500	Disposables
10	Vaginal Speculum (Small) Plastic	Piece	1,500	Disposables
11	Vaginal Speculum (Large)	Piece	500	Surg. Instrument
12	Vaginal Speculum (Medium)	Piece	500	Surg. Instrument
13	Vaginal Speculum (Small)	Piece	500	Surg. Instrument
14	Bed sheet, cotton or cotton blend (majority cotton), single-bed, 220 x 110 cm	Piece	2,000	Bedding
15	Disposable Waterproof Non-Woven Fabric Bed Sheet for Patients, Hospital Bed, Adults (Standard size)	Piece	3,000	Bedding
16	Hand Sanitizer, Alcohol 70-80%, 0.5 Ltr	Bottle	5,000	IPC
17	Sharps container, 3-5 L, cardboard	Box	1,000	IPC
<ul style="list-style-type: none"> • Puncture resistant • Maximum fill indicator • Temporary and permanent closure • Notches for removing needles from syringes • Disposable • Compliant with standards NF302, NFX 30-500 and ADR 				
18	HemoCue Hb 201 Microcuvettes, Strip (IVD Product - See required documentation)	Box of 50	500	Laboratory
19	HemoCue Hb 301 Microcuvettes(IVD Product - See required documentation)	Box of 50	500	Laboratory
<p>Product Description: Disposable capillary tubes (microcuvettes) used with Photometer HemoCue Hb 301 or equivalent. Very fine plastic tube provided with anticoagulant, designed to sample blood through capillarity. Used for determining haematocrit.</p> <p>Materials: Plastic microcuvette, Capacity: 8-10µl, Disposable, Anticoagulant: Heparin</p> <p>Chemistry Method: Determination of Hb and HbO2 at a single isobestic point using whole blood.</p> <p>Stability:</p>				

Annex 6 – Technical Specifications**ITB No. UNFPA/PAL/ITB/2024/012****LOT #2, 3 and 4 – Medical Supplies**

Item No.	Item	UoM	Quantity	Category
	<ul style="list-style-type: none"> Unopened: Store at 10-40°C (50-104°F) until expiry date printed on container. Short-term storage (6 weeks): -18-50°C (0.4-122°F). Stability once open: Stable for three months. <p>Instructions for Use: For use with HemoCue Hb 301 analyzer or equivalent for measuring whole blood haemoglobin. Used for determining haematocrit. Blood sample is drawn into the cavity by capillary action. Sample of venous or arterial blood may be used for testing. Should be stored at 10-40°C (50-104°F) until expiry date printed on container. Once opened, the microcuvettes are stable for three months.</p> <p>Supplied with: Manufacturer's instructions for use</p> <p>Packaging and Labelling:</p> <ul style="list-style-type: none"> Primary Packaging: 50 microcuvettes in a tube-shaped container (vial) with screw cap. Labelling on Primary Packaging: Name and/or trademark of the manufacturer . Manufacturer's product reference Type of product and main characteristics (dimensions, capacity). Expiry date by year and month prefixed by the word EXP (or equivalent harmonised symbol). Lot number prefixed by the word LOT (or equivalent harmonised symbol). Information for particular storage conditions (temperature, pressure, light, humidity, etc.) as appropriate (or equivalent harmonised symbol). Symbols used according to ISO 15223 and EN 980. CE mark Secondary Packaging: 4 containers (of 50 cuvettes each) in a box. Total of 200 microcuvettes in a box with manufacturer's instructions for use. Labelling on Secondary Packaging: Name and/or trademark of the manufacturer. Manufacturer's product reference Type of product and main characteristics (dimensions, capacity). Expiry date by year and month prefixed by the word EXP (or equivalent harmonised symbol). Lot number prefixed by the word LOT (or equivalent harmonised symbol). Information for particular storage conditions (temperature, pressure, light, humidity, etc.) as appropriate (or equivalent harmonised symbol). Number of units/pieces. Symbols used according to ISO 15223 and EN 980. CE mark <p>Regulation & Conformity Requirements: MDD) 98/79EEC CE self-declaration. ISO 13485 certificate</p> <p>Classification: In Vitro Device (other than specified in List A or List B Annex II IVD 98/79/EEC)</p> <p>Safety & Product Standards: Must comply with the following standards: ISO 13485:2003 Medical devices – Quality management systems – Requirements for regulatory purposes. ISO 14971:2007 Medical Devices – Application of risk management to medical devices. EN 13641:2002 Elimination or reduction of risk of infection related to in vitro diagnostic reagents. EN 14820:2004 Single-use containers for human venous blood specimen collection. ISO 18113-2:2009 In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 2: In vitro diagnostic reagents for professional use. ISO 12772:1997: Disposable microhematocrit capillary tubes</p> <p>Environmental Requirements: Not use PVC polymer</p>			
20	Placenta Pan / basin, stainless steel, 600-800 CC, with cover	Piece	100	Instruments
21	Ambu Bag, neonatal, 200–320 mL. Intake valve with optional nipple for O2 tubing: polycarbonate/ polysulfone or other material fulfilling the ISO 10651-4 or equivalent.	Piece	50	Instruments
22	Paper CTG, Thermal, Z-fold P4,	Stack	300	Medical Stationary

Annex 6 – Technical Specifications**ITB No. UNFPA/PAL/ITB/2024/012****LOT #2, 3 and 4 – Medical Supplies**

Item No.	Item	UoM	Quantity	Category
23	Autoclave Tape-Sterilization Tape (3/4" Wide) 50m	Roll	1,000	Medical Stationary
24	Syringe, Luer, 2 ml, sterile, single use	Each	62,400	Disposables

Product description:

For injection and various other uses, including mixing. Syringe options: two pieces (barrel with Luer nozzle & plunger) or three pieces (barrel with Luer nozzle, plunger & piston).

Barrel: With finger grip. Materials: medical grade PE (polyethylene) or PP (polypropylene); transparent for easy reading & detecting air bubbles. Cylindrical shape. Graduation scale: clear, water-resistant, with scale intervals of 0.5 & 1.0 ml increments between graduation lines to be numbered. Ends in a male Luer tip (conical with 6% taper). Luer nozzle situated centrally. Concentric Luer nozzle.

Plunger: Material: PP (polypropylene). Slides inside the barrel.

Gasket: Material: elastomer, medical grade. Located at the end of the plunger. Ensures a secure & safe seal.

Capacity: 2 ml., Sterile, single-use., Sterilisation method: Ethylene oxide.

Instructions for use: For injection and various other uses, including mixing.

Injection safety:

Syringe is sterile, ready for immediate use, and is for single use ONLY. Check integrity of packaging before opening. Do not use syringe if packaging is not sealed or is pierced. NEVER recap needle after use and IMMEDIATELY dispose of mounted syringe & needle into a puncture-proof safety container.

Supplied with: Manufacturer's instruction for use.

Accessories/spare parts/consumables: Syringe needle.

Packaging and labelling: Primary packaging: One (1) syringe packed in an individual sterilized peel-pack made of paper and/or plastic.

Labelling on the primary packaging:

- Name and/or trademark & address of manufacturer.
- Manufacturer's product reference.
- Type of product and main characteristics.
- Word sterile (or equivalent harmonized symbol).
- Sterilization method (or equivalent harmonized symbol).
- Lot number prefixed by the word LOT (or equivalent harmonized symbol).
- Expiry date by year and month prefixed by the word EXP (or equivalent harmonized symbol).
- Words or single use (or equivalent harmonized symbol).
- Words check the integrity of the individual sterilized pack before use (or equivalent harmonized symbol).

Symbols used according to ISO 15223 and EN 980: CE mark and Notified Body number.

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<p>Secondary packaging: Protected unit. 1 box of 100 blister-packed syringes. Protected unit: one (1) box 100-unit presentation; labelling is the same as that of primary packaging. Number of units per secondary packaging; information for product-specific storage conditions (e.g., temperature, pressure, light, humidity, etc.).</p> <p>Symbols used according to ISO 15223 and EN 980: CE mark, Notified Body number.</p> <p>Regulation & conformity requirements: CE mark conforming to Council Directive 93/42/EEC on Medical Devices. CE certificate (for Class Is with Notified Body number).</p> <p>Classification: Class Is – Class I sterile (sterile device MDD 93/42/EEC).</p> <p>Safety & product Standards: Must comply with the following standards:</p> <ul style="list-style-type: none">• ISO 13485:2003 Medical devices - Quality management systems -- Requirements for regulatory purposes• ISO 14971:2007 Medical Devices - Application of risk management to medical devices• ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process• ISO 7886-1: 1993/Coor 1:1995 Sterile hypodermic syringe for single use: part 1: syringe for manual use• ISO 594-1:1986 Conical fittings with a 6% (Luer) taper for syringes, needles, and certain other medical equipment - terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems, and packaging systems• ISO 11607-2:2006 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing, and assembly processes <p>Environmental requirements: Do not use PVC polymer.</p>				
25	Needle, Luer, 21G, sterile, single use	Each	235,200	Disposables
<p>Product description: Needle with base (Luer type fitting) and protective cap.</p> <p>Material: Needle: Stainless steel. Base and protective cap: plastic. Sterile single use (ethylene oxide sterilisation). External diameter expressed in Gauge and millimeters. Length expressed preferably in millimetres. Size: 21G (0.8 x 38-40mm). Cannula and tube: Made of stainless steel. Normal or thin-walled. Long bevelled (angle inferior or equal to 13°) or short bevelled (angle between 13° and 19°). Silicone-coated to facilitate insertion.</p> <p>Base: Allows the needle to be connected to a syringe or other injection devices. Formed by a conical female Luer connection. Designed in such a way that it prevents the needle from rolling on a flat surface. Made of polypropylene (PP). Internationally recognized colour code system allows easy identification of the hypodermic needles external diameter.</p> <p>Cap: The cap protects the cannula and its bevel and preserves the sterility of the needle. Made of polypropylene (PP).</p> <p>Instructions for use: For intramuscular (IM) injection: adults. For intra-arterial: adults children.</p> <p>Safety process: The needle is for single use only. When inserting a needle: use aseptic techniques.</p> <p>Supplied with: Manufacturers instruction for use.</p> <p>Packaging and labelling:</p> <p>Primary packaging: Unit of use. 1 needle packed in an individual sterilised peel-pack made of paper and/or plastic.</p>				

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Secondary packaging: Protected unit. 1 box of 100 blister packed needles.

Over packaging: Packaging unit. X (protected units) packed in (extra packaging) rigid packaging with or without plastic film.

Symbols used according to ISO 15223: CE mark with Notified Body number.

Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE Certificate (class IIa).

Classification: 93/42/EEC Class IIa – CE certificate.

Safety & product Standards: Must comply with the following standards: ISO 11607-1:2007 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems ISO 6009:1992 Hypodermic needles for single use -- Colour coding for identification EN 20594-1:1993 Conical fittings with a 6% (Luer) taper for syringes, needles, and certain other medical equipment - Part 1: General requirements (ISO 594-1:1986) ISO 7864:1993 Sterile hypodermic needles for single use.

Environmental requirements: Use of other polymer instead of PVC.

26	Cotton wool, 500 g, roll, non-sterile	Roll	732	Disposables
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Product description: Dressing material with high absorption used for cleaning wounds. Surgical quality 100% cotton.

Material: 100 % surgical hydrophilic cotton which has been carefully purified, bleached, and carded. Roll of 500 gram net weight. Not pre-cut. Non-sterile cotton wool: can also be used in sterile condition (after steam sterilisation). Single use.

Instructions for use: Dressing material with high absorption used for cleaning wounds. Non-sterile cotton wool: can also be used in sterile condition (after steam sterilisation). The size has been chosen as being the most commonly used.

Safety process: The cotton wool is for single use only. Collect and destroy by incineration in a controlled environment.

Supplied with: Manufacturers instruction for use.

Packaging and labelling: One (1) roll of cotton wool in a plastic bag.

Symbols used according to ISO 15223:

Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2003 certified.

Classification: 93/42/EEC Class I – Self declaration / CE certificate.

27	Syringe,disp,5ml,ster/BOX-100 Product Description: Syringe,disp,5ml,ster/BOX-100	Box of 100	228	Disposables
28	Tourniquet, latex rubber, 75 cm	Each	152	Disposables

Product description: Elastic strip used to compress a limb to stop blood flow. May be solid or tubular.

Material: Latex rubber. Autoclavable at 121°C. Length: 75 - 100 cm. Elastic strip solid width: approx. 18 - 20 mm. Elastic strip tubular inner diameter: approx. 7 mm. Elastic strip tubular outer diameter: approx. 10 mm. Reusable. Non-sterile.

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Instructions for use: A tourniquet is used to facilitate the puncture of veins.

Supplied with: Manufacturers instruction for use.

Packaging and labelling: One (1) Tourniquet in a plastic bag.

Symbols used according to ISO 15223:

Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2003 certified.

Classification: 93/42/EEC Class I – Self declaration / CE certificate.

29	Clamp, umbilical, 5.2 cm, sterile, single use	Each	13,200	Disposables
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Product description: Disposable sterile umbilical cord clamp safe effective and easy to apply. Safe security lock with a click to indicate correct locking to protect against accidental re-opening after clamping. Grooves all along the length to prevent slip of the umbilical cord and to retain it in the same position. Finger grip to ensure safe and easy handling.

Measurements: approx. 52 mm.

Material: Plastic (polymer) medical grade. DEHP free. Single-use. Sterile.

Supplied with: Manufacturers instruction for use.

Instructions for use: Disposable sterile umbilical cord clamp safe effective and easy to apply designed for clamping the umbilical cord soon after the birth. CE mark and reference number of notifying body.

Packaging & Labelling: One (1) umbilical cord clamp in an individual sterilised peel pack.

Symbols used according to ISO 15223 and EN 15986:2011: CE mark and reference number of notifying body.

Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE certificate (class Is) ISO 13845:2003 certified.

Classification: Class Is (I sterile) - Medical Device Directive 93/42/EEC.

Safety & product Standards: Must comply with the following standards: ISO 13485: 2003, ISO 10993-1:2009, ISO 10993-7:2008.

Environmental requirements: PP PE polymer not PVC PHT free.

30	Cannula, IV short, 20G, sterile, single use	Each	21,600	Disposables
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Product description: Sterile Intravenous (IV) cannula to be introduced into a peripheral vein for infusing fluids, administering IV drugs, transfusing blood, and blood products (for adult and infant use).

Material for trocar: Stainless steel.

Material for cannula: PTFE (Poly Tetra Fluoro Ethylene), FEP (Fluorinated Ethylene Propylene), PUR (Polyurethane). DEHP free.

Size: 20G (1 x 32mm) pink.

Flow rate: approx. 55ml/min.

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Colour code/external diameter: Visible at the base of cannula. Cannula with fine and tapered walls perfectly adjusted to the needle.

Distal end: straight and tapering.

Proximal end: base fitted with luer lock connector, 2 grapping wings (butterfly) standardized colour code depending on the diameter. Fitted with a lateral injection port.

Injection port: fitted with silicone anti-reflux valve cap with colour code and chimney of luer type.

Protecting cap: Stopper fitted with a hydrophobic membrane with micro-perforations to let the air flow while stopping blood male luer connection.

Triple-bevelled trocar.

Transparent female luer base.

Components: Protecting cap, trocar, cannula, stopper, injection port, Luer lock (all parts fit together to form a unit). Sterile and single use.

Initial sterilisation method: Ethylene oxide gas.

Instructions for use: Sterile IV cannula to be introduced into a peripheral vein for infusing fluids, administering IV drugs, transfusing blood, and blood products.

Safety process: IV cannula is for single use only. Rules of asepsis must be followed when inserting IV cannula. IV cannula should not be left in situ for more than 72 hours. It should be removed immediately in case of infection signs.

Supplied with: Manufacturers instruction for use.

Packaging and labelling:

Primary packaging: Unit of use. One (1) IV cannula in an individual sterilised peel pack.

Secondary packaging: Protected unit. One (1) box of 50 IV cannulas.

Symbols used according to ISO 15223: CE Mark and Notified Body number.

Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE Certificate (class IIa).

Classification: Class IIa - Medical Device Directive 93/42/EEC.

Safety & product Standards: Must comply with the following standards:

- ISO 10555-5:2013 Intravascular catheters -- Sterile and single-use catheters -- Part 5: Over-needle peripheral catheters.
- ISO 594-1:1986 (BS EN 20594-1:1994) Conical fittings with a 6% (Luer) taper for syringes, needles, and certain other medical equipment -- Part 1: General requirements.
- ISO 11607-1:2007 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems, and packaging systems.
- ISO 11607-2:2006 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing, and assembly.

31	Syringe,disp,10ml,ster/BOX-100 Product Description: Syringe,disp,10ml,ster/BOX-100	Box of 100	632	Disposables
32	Syringe,disp,1ml,ster/BOX-100 Product Description: Syringe,disp,1ml,ster/BOX-120	Box of 100	264	Disposables

Product description: For injection and various other uses including mixing.

Syringe types: Two pieces: barrel with Luer nozzle & plunger, or three pieces: barrel with Luer nozzle, plunger & piston.

Barrel: With finger grip. Materials: medical grade PE (polyethylene) or PP (polypropylene); transparent for easy reading & for detecting air bubbles. Cylindrical shape. Graduation scale: clear, water resistant with scale interval of 0.01 ml (3-piece syringe) or 0.05 ml (2-piece syringe). Ends in a male Luer tip (conical with 6% taper). Luer nozzle shall be situated centrally.

Plunger: Material: PP (polypropylene). Slides inside the barrel.

Gasket: Material: elastomer medical grade. Located at the end of plunger. Ensures a secure and safe seal.

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- Syringe is sterile, ready for immediate use & is for single use ONLY.
- Check integrity of packaging before opening.
- Do not use syringe if packaging is not sealed or is pierced.
- NEVER recap needle after use and IMMEDIATELY dispose of the mounted syringe and needle into a puncture-proof safety container.

Supplied with: Manufacturers instruction for use.**Accessories/ spare parts/ consumables:** Syringe needle.**Packaging and labelling:**

- **Primary packaging:** One (1) syringe packed in individual sterilized peel-pack made of paper and/or plastic.
- **Labelling on primary packaging:**
 - Name and/or trademark & address of manufacturer.
 - Manufacturers product reference.
 - Type of product and main characteristics.
 - Word "sterile" (or equivalent harmonised symbol).
 - Sterilisation method (or equivalent harmonised symbol).
 - Lot number prefixed by word "LOT" (or equivalent harmonised symbol).
 - Expiry date by year & month prefixed by word "EXP" (or equivalent harmonised symbol).
 - Words "single use" (or equivalent harmonised symbol).
 - Words "check the integrity of the individual sterilised pack before use" (or equivalent harmonised symbol).
- Symbols used according to ISO 15223 and EN 980. CE mark and Notified Body number.
- **Secondary packaging:** Protected unit. One box of 100 blister-packed syringes.
 - Protected unit one (1) box 100-unit presentation; labelling is the same as for primary packaging.
 - Number of units per secondary packaging information for product-specific storage conditions (e.g. temperature, pressure, light, humidity, etc.).
- Symbols used according to ISO 15223 and EN 980. CE mark and Notified Body number.

Regulation & conformity requirements: CE mark conforming to Council Directive 93/42/EEC on Medical Devices. CE certificate (for Class Is with Notified Body number).**Classification:** Class Is – Class I sterile (sterile device MDD 93/42/EEC).**Safety & product Standards:** Must comply with the following standards:

- ISO 13485:2003 Medical devices - Quality management systems -- Requirements for regulatory purposes.

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- ISO 14971:2007 Medical Devices - Application of risk management to medical devices.
- ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
- ISO 7886-1:1993/Coor 1:1995 Sterile hypodermic syringe for single use: Part 1: Syringe for manual use.
- ISO 594-1:1986 Conical fittings with a 6% (Luer) taper for syringes, needles, and certain other medical equipment -- Part 1: General requirements.
- ISO 11607-1:2007 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems, and packaging systems.
- ISO 11607-2:2006 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing, and assembly processes.

Environmental requirements: Not to use PVC polymer.

33	Needle, Luer, 25G, sterile, single use	Each	29,200	Disposables
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Product description: Needle w/base (Luer type fitting) & protective cap.**Materials:** **Needle:** Stainless steel. **Base & protective cap:** Medical grade plastic.**Sterilisation:** Sterile single-use (ethylene oxide sterilisation).**Specifications:**

- External diameter expressed in gauge & millimeters.
- Length expressed preferably in millimeters.
- Size: 25 G (0.5 x 25mm).
- Non-toxic.
- Pyrogen-free.

Cannula & tube:

- Made of stainless steel.
- Normal & thin-walled.
- Long bevelled (angle inferior or equal to 13°) or short bevelled (angle between 13° and 19°).
- Silicone coated to facilitate insertion.

Base:

- Allows needle to be connected to syringe/other injection devices.
- Formed by conical female Luer connection.
- Prevents needle from rolling on flat surface.
- Made of polypropylene (PP).

Colour Coding: Internationally recognized colour code system allows easy identification of hypodermic needles' external diameter.**Cap:**

- Protects cannula & its bevel and preserves sterility of needle.
- Made of polypropylene (PP).

Supplied with: Manufacturer's instructions for use may be printed onto primary packaging or provided on a separate insert.**Languages:** English and/or Arabic**Accessories (available but not supplied):** N/A**Intended use:**

- For subcutaneous or intramuscular (SCIM) injection: adults.
- For intravenous (IV) injection: children.
- For intramuscular (IM) injection: children and infants.
- For intra-arterial: adults and children.

Safety process:

<div><ul style="list-style-type: none">• Needle is for single use only.• When inserting needle: use aseptic techniques.<p>Packaging & Labelling:</p><ul style="list-style-type: none">• Primary packaging: Unit of use. One (1) needle packed in individual sterilized peel pack made of paper and/or plastic.• Secondary packaging: Protected unit. One (1) box of hundred (100) blister-packed needles.• Primary package label includes:<ul style="list-style-type: none">○ Device identity & intended purpose.○ Manufacturer's product code or reference number.○ Manufacturer identification.○ Address of manufacturing site.○ EC Rep identification.○ How device should be used, maintained & stored.○ Lot/Batch & MFD and EXP.○ Any residual device risks, warnings, limitations, or contraindications.• Symbols used: According to ISO 15223. CE mark.<ul style="list-style-type: none">○ Word "sterile" (or equivalent harmonised symbol).○ Sterilisation method (or equivalent harmonised symbol).○ Words "for single use" (or equivalent harmonised symbol).○ Words "check the package integrity before use" or similar warning.○ Words "dispose after use" if space allows.• Secondary package label includes: Number of units.<p>Regulation and Conformity Requirements:</p><ul style="list-style-type: none">• CE mark (conforming to MD Directive MDD 93/42/EEC MDR 2017/745) or FDA 510k approved or equivalent.• Declaration of Conformity according to ISO 17050.• ISO 13485.<p>Classification: Class IIa sterile (MDD 93/42/EEC MDR 2017/745).</p><p>Safety & Product Standards (current versions):</p><ul style="list-style-type: none">• ISO 11135: Sterilization of health-care products - Ethylene oxide.• ISO 11607-1: Packaging for Terminally sterilized MDs - Part 1: Requirements for materials, sterile barrier systems, & packaging systems.• ISO 11607-2: Packaging for terminally sterilized MDs — Part 2: Validation requirements for forming, sealing, & assembly processes.• ISO 6009: Hypodermic needles for single use - Colour coding for identification.• ISO 7864: Sterile hypodermic needles for single use.• ISO 80369-1: Small-bore connectors for liquids & gases in healthcare applications — Part 1: General requirements.• ISO 80369-7: Small-bore connectors for liquids & gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications.• ISO 23908: Sharps protection features for single-use hypodermic needles, introducers for catheters & needles used for blood sampling.• ISO 9626-1: Stainless steel needle tubing for manufacture of MDs — Requirements & test methods.• ISO 10993-1: Biological evaluation of MDs - Part: Evaluation & testing within a risk management process.<p>Environmental Requirements: Use of other polymer instead of PVC. ISO 14001: Environmental management.</p></div>				
34	Syringe, feeding, catheter tip, 50 ml, sterile, single use	Each	760	Disposables

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35	Gloves, surgical, size 7, powder free, sterile, single use	Each	16,120	Disposables
<p>Product description: Pair of surgical gloves anatomically shaped: 1 right-handed and 1 left-handed. Waterproof and stretch proof.</p> <p>Material: Natural latex. Powder-free.</p> <p>Size selected: Surgical gloves size: 7. Total length: approximately 270mm. Width: approximately 89 +/- 5mm.</p> <p>Sterilisation: Sterile and single use. Initial sterilization method: Ethylene oxide gas or Gamma radiation.</p> <p>Instructions for use: Sterile single-use gloves used for surgical procedures to protect both the patient and medical staff from cross-contamination. Surgical gloves are sterile and strictly SINGLE USE. This item must be ordered in sufficient quantity to encourage its use. The sizes have been chosen as being the most commonly used.</p> <p>Supplied with: Manufacturer's instructions for use.</p> <p>Packaging and labelling:</p> <ul style="list-style-type: none"> • Primary packaging: Unit of use. One (1) pair of gloves in an individual sterilised peel pack. Supplied with double packaging: one interior layer plus sterilised peel-pack. Packed in the interior layer: right and left hand with the sleeves reversed up to the thumb. Labelled with size, right hand, left hand, and position of the sleeves. • Secondary packaging: Protected unit. One (1) box of 50 pairs of gloves. <p>Symbols used: According to ISO 15223, CE Mark with Notified Body number.</p> <p>Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC. CE Certificate (Class IIa).</p> <p>Classification: Class IIa - Medical Device Directive 93/42/EEC.</p> <p>Safety & product standards: Must comply with the following standards:</p> <ul style="list-style-type: none"> • ISO 11607-1:2007 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems, and packaging systems. • EN 455-1:2000 Medical gloves for single use - Part 1: Requirements and testing for freedom from holes. • EN 455-2:2009+A2:2013 Medical gloves for single use - Requirements and testing for physical properties. • EN 455-3:2006 Medical gloves for single use - Part 3: Requirements and testing for biological evaluation. • EN 455-4:2009 Medical gloves for single use - Requirements and testing for shelf life determination. • ISO 12243:2003 Medical gloves made from natural rubber latex - Determination of water-extractable protein using the modified Lowry method. 				
36	Gloves, gynaecological, medium, powder free, sterile	Each	660	Disposables
<p>Product description: Pair of gynaecological gloves with long cuff anatomically shaped: 1 right-handed and 1 left-handed. Waterproof and stretch proof.</p> <p>Material: Natural latex. Powder-free.</p> <p>Size selected: Gynaecological gloves size: medium (7.5-8). Total length: approximately 400mm. Palm width: approximately 95 +/- 5mm. Thickness: cuff minimum 0.12mm; palm minimum 0.16mm; fingers minimum 0.18mm.</p> <p>Sterilisation: Sterile and single use. Initial sterilisation method: Ethylene oxide gas or Gamma radiation.</p>				

Instructions for use: Sterile single-use gloves with long cuff used for gynaecological and obstetric procedures to protect both the patient and medical staff from cross-contamination. Gynaecological gloves, also named long cuff gloves, are sterile and strictly SINGLE USE. This item must be ordered in sufficient quantity to encourage its use. The sizes have been chosen as being the most commonly used.

Supplied with: Manufacturer's instructions for use.

Packaging and labelling:

- **Primary packaging:** Unit of use. One (1) pair of gloves in an individual sterilised peel pack. Supplied with double packaging: one interior layer plus sterilised peel-pack. Packed in the interior layer: right and left hand with the sleeves reversed up to the thumb. Labelled with size, right hand, left hand, and position of the sleeves.
- **Secondary packaging:** Protected unit. One (1) box of 25 or 50 pairs of gloves.

Symbols used: According to ISO 15223, CE Mark with Notified Body number.

Regulation & conformity requirements: CE mark conforming to Council Directive 93/42/EEC on Medical Devices. CE certificate (for Class Is with Notified Body number).

Classification: Class Is – Class I sterile (sterile device MDD 93/42/EEC).

Safety & product standards: Must comply with the following standards:

- ISO 11607-1:2007 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems, and packaging systems.
- EN 455-1:2000 Medical gloves for single use - Part 1: Requirements and testing for freedom from holes.
- EN 455-2:2009+A2:2013 Medical gloves for single use - Requirements and testing for physical properties.
- EN 455-3:2006 Medical gloves for single use - Part 3: Requirements and testing for biological evaluation.
- EN 455-4:2009 Medical gloves for single use - Requirements and testing for shelf life determination.
- ISO 12243:2003 Medical gloves made from natural rubber latex - Determination of water-extractable protein using the modified Lowry method.

37	Suture, absorbable, DEC3(2-0), 3/8, 30 mm, round, sterile	Each	2,736	Disposables
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Product description: Absorbable synthetic braided suture for holding wounds in apposition until natural healing sufficiently progresses to eliminate the need for suture support. Made from PGA (polyglycolic acid) or polyglactine, this thread is a slow-absorption type, absorbed after approximately 21 days. Selected over catgut due to reduced risks of inflammation and contamination.

Thread specifications: **Type:** Absorbable synthetic braided thread. **Material:** PGA polyglycolic acid polyglactine. **Gauge:** DEC 3 (2/0). **Length:** Approx. 75 cm

Needle specifications: **Type:** Eyeless, pre-attached to thread. **Point:** Round (non-cutting) for reduced tissue trauma. **Curvature:** 3/8 circle, treated stainless steel. **Length:** Approx. 30 mm

Shelf life and sterility: Minimum 5-year shelf life, sterile, and single-use only. Initial sterilization method: Ethylene oxide gas or gamma irradiation.

Intended use: Primarily for peritoneal digestive sutures, ideal for applications requiring slow absorption.

Storage conditions: Avoid exposure to extreme temperatures and humidity levels. Inspect packaging integrity before use, and discard if damaged.

<p>Safety and handling: For single-use only; do not re-sterilize. Practice strict aseptic techniques during suturing. To prevent needle-stick injuries, use curved, round-point needles and handle with surgical gloves, needle holders, and standard tissue forceps. After use, place sutures in a sealed container for disposal by incineration in a controlled environment.</p> <p>Packaging and labeling:</p> <ul style="list-style-type: none">• Primary packaging: Individual sterile peel pack, one absorbable suture per unit. Label includes manufacturer’s name, product reference, thread composition, gauge, needle type and size, sterilization and expiration details, CE mark with Notified Body number, and single-use indicator.• Secondary packaging: Box containing 12 sutures with the same labeling as primary packaging. Also includes unit quantity, storage conditions, and handling instructions. <p>Regulation and conformity: CE marked per Medical Device Directive 93/42/EEC, with CE Certificate (Class III) and CE Dossier Design certificate.</p> <p>Safety and product standards: Conforms to the following ISO standards:</p> <ul style="list-style-type: none">• ISO 13485:2003 for medical device quality management• ISO 10993-1:2009 for biological evaluation of medical devices• ISO 10334:1994 for malleable surgical sutures• ISO 11607-1:2007 for packaging requirements of terminally sterilized devices				
38	Extractor, mucus, 20 ml, sterile, single use	Each	3,800	Disposables
<p>Product description: Sterile mucus extractor device used for aspirating secretions or other liquids obstructing the pharynx or airways in newborn babies to ensure free respiration. Transparent container to permit immediate visual examination of the mucus.</p> <p>Catheter size selected: CH12 with open end smooth round tip for trauma-free insertion, distal end with conical tip. Single chamber container plastic. Capacity: approx. 20 ml. With filter to prevent entry of mucus to user's mouth during suction. Sterile and single-use.</p> <p>Initial sterilisation method: Ethylene oxide gas or Gamma radiation.</p> <p>Instructions for use: Sterile mucus extractor device used for aspirating secretions or other liquids obstructing the pharynx or airways. The sterile suction tube device is introduced either via the mouth or nose through the channel of an endotracheal tube or tracheotomy tube. The size has been chosen as being the most commonly used.</p> <p>Safety process: The mucus extractor is for single use only. When inserting a suction tube, use clean techniques. Collect and destroy by incineration in a controlled environment.</p> <p>Supplied with: Manufacturer's instructions for use.</p> <p>Packaging and labelling:</p> <ul style="list-style-type: none">• Primary packaging: Unit of use. One (1) mucus extractor in an individual sterilised peel pack.• Secondary packaging: Protected unit. One (1) box of 50 mucus extractors. <p>Symbols used: According to ISO 15223, CE mark.</p> <p>Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC, CE self-declaration. ISO 13845:2003 certified.</p> <p>Classification: 93/42/EEC Class I – Self-declaration / CE cert.</p> <p>Safety & product standards: Must comply with the following standards:</p>				

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- ISO 11607-1:2007 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems, and packaging systems.

Environmental requirements: It is recommended to use other polymers, not PVC.

39	Tube, suction, CH10, 50-cm long, conical tip, sterile	Tube	2,440	Disposables
<p>Product description: Sterile suction for aspiration of pus, blood, secretions, food, or other substances obstructing the pharynx or airway. Sterile suction catheter for single use.</p> <p>Material: Polyvinyl chloride (PVC) DEHP-free.</p> <p>Diameter size: Diameter expressed in Charriere French gauge. Gauge CH10.</p> <p>Length: Length expressed in cm. Length approx. 50 cm.</p> <p>Tube: Straight distal end with 2 side windows.</p> <p>Cup connector: Conical tip.</p> <p>Colour code/external diameter: Visible on cup connector. The suction tube consists of a single channel tube with an open distal end with side windows. Proximal end with cup connector (conical tip) allowing the tube to be connected to devices such as suction pump systems.</p> <p>Disposable: Single-use. Sterile.</p> <p>Initial sterilisation method: Ethylene oxide gas.</p> <p>Instructions for use: Sterile suction tube device used for aspirating pus, blood, secretions, food, or other liquids obstructing the pharynx or airways. The sterile suction tube device is introduced either via the mouth or nose through the channel of an endotracheal tube or tracheotomy tube. The size has been chosen as being the most commonly used.</p> <p>Conditions for stock: Avoid storage at extreme temperatures and humidity levels. Check the integrity of each unit before use. Single-use material supplied in sterile packaging. Do not use if the packaging is damaged.</p> <p>Safety process: The suction tube is for single use only. When inserting a suction tube, use clean techniques. Collect and destroy by incineration in a controlled environment.</p> <p>Supplied with: Manufacturer's instructions for use.</p> <p>Packaging and labelling:</p> <ul style="list-style-type: none">• Primary packaging: One (1) suction tube packed in an individual sterilised peel-pack made of paper and/or plastic.• Labelling on the primary packaging:<ul style="list-style-type: none">○ Name and/or trademark and address of the manufacturer.○ Manufacturer's product reference.○ Type of product and main characteristics.○ The word sterile (or equivalent harmonised symbol).○ Sterilisation method (or equivalent harmonised symbol).○ Lot number prefixed by the word LOT (or equivalent harmonised symbol).○ Expiry date by year and month prefixed by the word EXP (or equivalent harmonised symbol).				

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- The words "single use" (or equivalent harmonised symbol).
- The words "check the integrity of the individual sterilised pack before use" (or equivalent harmonised symbol).

Symbols used: According to ISO 15223 and EN 980, CE mark and Notified Body number.

Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC, CE Certificate (class IIa).

Classification: 93/42/EEC Class IIa – CE certificate.

Safety & product standards: Must comply with the following standards:

- ISO 13485:2003 Medical devices - Quality management systems -- Requirements for regulatory purposes.
- ISO 14971:2007 Medical Devices - Application of risk management to medical devices.
- ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
- ISO 10079-3:2009 Medical suction equipment — Part 3: Suction equipment powered from a vacuum or pressure source.
- EN 1782:1998+A1:2009 Tracheal tubes and connectors.
- ISO 11607-1:2007 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems, and packaging systems.
- ISO 11607-2:2006 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming sealing and assembly processes.

Environmental requirements: Not to use PVC polymer.

40	Tube, suction, CH14, 50-cm long, conical tip, sterile	Tube	2,440	Disposables
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Product description: Sterile suction for aspiration of pus, blood, secretions, food, or other substances obstructing the pharynx or airway. Sterile suction catheter for single use.

Material: Polyvinyl chloride (PVC) DEHP-free.

Diameter size: Diameter expressed in Charriere French gauge. Gauge CH14.

Length: Length expressed in cm. Length approx. 50 cm.

Tube: Straight distal end with 2 side windows.

Cup connector: Conical tip.

Colour code/external diameter: Visible on cup connector. The suction tube consists of a single channel tube with an open distal end with side windows. The proximal end has a cup connector (conical tip) allowing the tube to be connected to devices such as suction pump systems.

Disposable: Single-use. Sterile.

Initial sterilisation method: Ethylene oxide gas.

Instructions for use: Sterile suction tube device used for aspirating pus, blood, secretions, food, or other liquids obstructing the pharynx or airways. The sterile suction tube device is introduced either via the mouth or nose through the channel of an endotracheal tube or tracheotomy tube. The size has been chosen as being the most commonly used.

Conditions for stock: Avoid storage at extreme temperatures and humidity levels. Check the integrity of each unit before use. Single-use material supplied in sterile packaging. Do not use if the packaging is damaged.

Safety process: The suction tube is for single use only. When inserting a suction tube, use clean techniques. Collect and destroy by

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<p>incineration in a controlled environment.</p> <p>Supplied with: Manufacturer's instructions for use.</p> <p>Packaging and labelling: Primary packaging: One (1) suction tube packed in an individual sterilised peel-pack made of paper and/or plastic. Labelling on the primary packaging: Name and/or trademark and address of the manufacturer; manufacturer's product reference; type of product and main characteristics; the word "sterile" (or equivalent harmonised symbol); sterilisation method (or equivalent harmonised symbol); lot number prefixed by the word "LOT" (or equivalent harmonised symbol); expiry date by year and month prefixed by the word "EXP" (or equivalent harmonised symbol); the words "single use" (or equivalent harmonised symbol); the words "check the integrity of the individual sterilised pack before use" (or equivalent harmonised symbol).</p> <p>Symbols used: According to ISO 15223 and EN 980, CE mark, and Notified Body number.</p> <p>Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC, CE Certificate (class IIa).</p> <p>Classification: 93/42/EEC Class IIa – CE certificate.</p> <p>Safety & product standards: Must comply with the following standards: ISO 13485:2003 Medical devices - Quality management systems - Requirements for regulatory purposes; ISO 14971:2007 Medical Devices - Application of risk management to medical devices; ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process; ISO 10079-3:2009 Medical suction equipment — Part 3: Suction equipment powered from a vacuum or pressure source; EN 1782:1998+A1:2009 Tracheal tubes and connectors; ISO 11607-1:2007 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems, and packaging systems; ISO 11607-2:2006 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming sealing and assembly processes.</p> <p>Environmental requirements: Not to use PVC polymer.</p>				
41	Catheter, urethral, CH12, sterile	Each	1,520	Disposables
<p>Product description: Sterile urethral catheter device designed to be introduced into the bladder cavity to drain off urine before delivery.</p> <p>Material: Polyvinyl chloride (PVC) DEHP-free.</p> <p>Flexible catheter: Nelaton type = without balloon. Transparent. Central channel for urinary drainage. Rounded distal end with 2 side windows. Proximal end with cup connector allowing catheter to be connected with a urine bag.</p> <p>Size: Diameter expressed in Charriere French gauge. Size CH12.</p> <p>Length: Length expressed in cm. Length: 30 to 40 cm. Sterile and single use.</p> <p>Initial sterilisation method: Ethylene oxide gas.</p> <p>Instructions for use: Sterile urethral catheter device designed to be introduced into the bladder cavity to drain off urine before delivery. If lubrication is necessary to help introduce the catheter, the substance used must not cause physical or chemical changes to the catheter. If necessary, use sterile water. The size has been chosen as being the most commonly used.</p> <p>Safety process: This urethral catheter is for single use. When inserting a urethral catheter, use strict aseptic techniques.</p> <p>Supplied with: Manufacturer's instructions for use.</p> <p>Packaging and labelling: Primary packaging: One (1) urethral catheter in an individual sterilised peel pack. Secondary packaging: One (1) box of 50 urethral catheters.</p>				

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Symbols used: According to ISO 15223, CE Mark, and Notified Body number.

Regulation & conformity requirements: CE mark conforming to Council Directive 93/42/EEC on Medical Devices, CE certificate (for Class Is with Notified Body number).

Classification: Class Is – Class I sterile (sterile device MDD 93/42/EEC).

Safety & product standards: Must comply with the following standards: EN 1616:1997: Sterile urethral catheters for single use; ISO 11607-1:2007 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems, and packaging systems; ISO 11607-2:2006 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming sealing and assembly processes.

Environmental requirements: Use of other polymer instead of PVC.

42	Gauze, compress, 10 × 10 cm, sterile	Each	62,000	Disposables
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Product description: Gauze compress surgical folding, i.e., no free threads apparent after folding or when the first outside fold is opened.

Material: Absorbent gauze 100% cotton.

Components: Bleached purified textile plain weave. Compress gauze folded. Non-detectable by X-ray.

Thread count: Warp: 95 to 105 threads/dm, Weft: 66 to 74 threads/dm.

Weight: 23 g/m².

Type of gauze: 17 threads/cm² (grammage 23 g/m²).

Number of folds (thickness): 12.

Width: Approx. 10 cm.

Length: Approx. 10 cm.

Sterility: Non-sterile and single use.

Instructions for use: Dressing material used for cleaning wounds, disinfecting healthy skin, protecting wounds, etc.; non-sterile gauze compress of 17 threads and 12 folds has been selected as it can also be used for surgery in sterile conditions (after steam sterilisation). The size has been chosen as being the most commonly used.

Supplied with: Manufacturer's instructions for use.

Packaging and labelling: Primary packaging: One (1) plastic or paper pack of 100 compresses gauze bandages in a plastic bag.

Symbols used: According to ISO 15223, CE mark.

Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC, CE self-declaration, ISO 13845:2003 certified.

Classification: 93/42/EEC Class I – Self-declaration / CE cert.

Safety & product standards: Must comply with the following standards: BS EN 14079:2003 Non-active medical devices. Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze; EN 13726-1:2002 Test methods for primary wound dressings - Part 1.

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43	Tape, adhesive, zinc oxide, 2.5 cm × 5 m	Each	1,780	Disposables
<p>Product description: Components: Aerated and perforated textile strip impregnated with adhesive. High cutaneous tolerance. Non-stretch. Can be torn by hand. Impermeable to water. Must adhere strongly when applied to the skin but can be removed without causing significant lesions.</p> <p>Material: Textile strip: woven acetate taffeta. Adhesive: mixture of rubber resins and lanolin. Traditionally incorporates zinc oxide.</p> <p>Colour: White or flesh coloured.</p> <p>Length: Approximately 5 m.</p> <p>Width: Approximately 2 - 2.5 cm.</p> <p>Sterility: Non-sterile and single use.</p> <p>Instructions for use: Adhesive tape used for fixing dressings and appliances to the skin. Zinc oxide tape has been selected because it is inexpensive. Woven adhesive tape, like Micropore type, is very difficult to stick without ether. The quality is difficult to judge, and the adhesive can deteriorate seriously under exposure to heat and dampness. Make sure the storage conditions are observed to obtain maximum use of the item and avoid waste. The size has been chosen as being the most commonly used. Tape adhesive zinc oxide 2.5 cm x 5 m for basic and small wound dressing.</p> <p>Supplied with: Manufacturer's instructions for use.</p> <p>Packaging and labelling: Primary packaging: Unit of use. One (1) adhesive tape in a plastic bag. Secondary packaging: Protected unit. Ten (10) adhesive tapes in a box.</p> <p>Symbols used: According to ISO 15223, CE Mark.</p> <p>Regulation & conformity requirements: CE mark in conformity with Council Directive 93/42/EEC on Medical Devices.</p> <p>Classification: 93/42/EEC Class I – Self-declaration / CE cert.</p>				
44	Suture, absorbable, DEC4(1), 3/8, 36 mm, triangular, sterile	Each	10,080	Disposables
<p>Product description: Absorbable synthetic braided suture designed to hold wounds in apposition until natural healing sufficiently advances, eliminating the need for continued support from suture materials. Made from PGA (polyglycolic acid) or polyglactine, this thread is a slow-absorption type, with absorption completing around 21 days. Preferred over catgut, which poses higher contamination risks and potential for inflammation or rejection.</p> <p>Thread specifications: Type: Absorbable synthetic braided thread. Gauge: DEC4 (1/0) expressed in decimal gauge and traditional numbering. Length: Approximately 75 cm.</p> <p>Needle specifications: Eyeless with pre-attached thread, triangular point to ease passage through skin. Curved in a 3/8 circle, made from treated stainless steel, and approximately 36 mm in length.</p> <p>Shelf life and sterility: Minimum 5-year shelf life. Sterile, single-use only. Initial sterilization method: Ethylene oxide gas or gamma irradiation.</p> <p>Intended Use: Primarily used for internal sutures; suitable for slow absorption needs, reducing inflammation and risk of tissue trauma.</p> <p>Storage requirements: Store at stable temperatures and humidity. Ensure package integrity before use; single-use items must be discarded if the packaging is compromised.</p>				

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Safety and handling: Single-use only, cannot be re-sterilized. Adhere to strict aseptic techniques during use. To prevent injuries, use surgical gloves, needle holders, and standard forceps. Dispose of used sutures in a sealed container and incinerate under controlled conditions.

Packaging and labeling:
Primary packaging is an individual sterile peel pack containing one absorbable suture. Primary labeling includes manufacturer’s name, product reference, thread composition, gauge, needle type and size, sterilization and expiration symbols, CE mark with Notified Body number, and single-use indication. Secondary packaging consists of one box containing 12 absorbable sutures with labeling consistent with the primary packaging. Additional details on secondary packaging include unit quantity and storage conditions.

Regulation and conformity: CE mark per Medical Device Directive 93/42/EEC, with CE Certificate (Class III) and CE Dossier Design certificate.

Safety and product standards: Conforms to ISO standards, including ISO 13485 for medical device quality management, ISO 10993 for biological evaluation, ISO 10334 for malleable surgical sutures, and ISO 11607-1 for terminal sterilization packaging. Environmental compliance excludes PVC use.

45	Suture, absorbable, DEC3(2-0), 1/2, 30 mm, round, sterile	Each	9,744	Disposables
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Product description: Absorbable synthetic braided thread made from polyglycolic acid (PGA) or polyglactine.

- **Thread type:** Absorbable synthetic braided thread.
- **Gauge of thread:** Expressed in decimal gauge (DEC number) and traditional thread numbering; DEC3 (2/0).
- **Length of thread:** Approx. 75 cm.

Needle specifications: **Type:** Curved needle, 1/2 circle., **Point:** Round., **Needle length:** Approx. 30 mm.

Shelf life: Minimum of 5 years.

Sterility: Sterile, single-use.

Sterilization method: Ethylene oxide gas or gamma irradiation.

Absorption period: Absorbs gradually, approximately within 21 days.

Instructions for use:

- Suitable for peritoneal and digestive suturing.
- Suture length averages 75 cm, with a round needle point designed to minimize tissue trauma.
- This synthetic suture is slowly absorbable, reducing the need for removal.

Safety process: For single use only., Follow strict aseptic techniques when suturing.

Supplied with: Manufacturer’s instructions for use.

Packaging & Labelling:

- **Primary packaging:** One (1) absorbable suture in an individual sterilized peel pack.
- **Secondary packaging:** One (1) box of 36 absorbable sutures.
- **Labeling:** CE mark with Notified Body number, compliant with ISO 15223 symbols.

Regulation & Conformity requirements:

- CE mark in line with Medical Device Directive 93/42/EEC.
- CE Certificate for Class III with CE Dossier Design certificate.

Safety & Product Standards: Complies with ISO 11607-1:2007, Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems, and packaging systems.

46	Suture, absorbable, DEC3(2-0), 3/8, 50 mm, round, sterile	Each	2,016	Disposables
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Product description: Absorbable synthetic braided suture designed to hold wounds in apposition until natural healing progresses enough to eliminate the need for suture support. Made from PGA (polyglycolic acid) or polyglactine, this thread is a slow-absorption type with absorption completing around 21 days, chosen over catgut to reduce inflammation and contamination risks.

Thread specifications: Type: Absorbable synthetic braided thread. Material: PGA polyglycolic acid polyglactine. Gauge: DEC3 (2/0), expressed in decimal gauge and traditional numbering. Length: Approximately 75 cm.

Needle specifications: Eyeless, pre-attached thread, round-point (non-cutting) needle to minimize tissue trauma. Curved in a 3/8 circle, treated stainless steel, approximately 50 mm in length.

Shelf life and sterility: Minimum 5-year shelf life. Sterile, single-use only. Initial sterilization method: Ethylene oxide gas or gamma irradiation.

Intended use: Primarily used for peritoneal digestive sutures; suitable for slow absorption requirements, reducing trauma to tissues.

Storage requirements: Store at stable temperatures and humidity levels. Check packaging integrity before use; discard if compromised.

Safety and handling: For single-use only, do not re-sterilize. Use aseptic techniques during suturing. To prevent injuries, use surgical gloves, needle holders, and standard tissue forceps. After use, dispose of sutures in a sealed container and incinerate in a controlled environment.

Packaging and labeling:
Primary packaging is an individual sterile peel pack containing one absorbable suture. Labeling includes manufacturer’s name, product reference, thread composition, gauge, needle type and size, sterilization and expiration symbols, CE mark with Notified Body number, and single-use indication. Secondary packaging consists of one box containing 12 absorbable sutures with the same labeling as the primary packaging, plus information on unit quantity and storage conditions.

Regulation and conformity: CE mark per Medical Device Directive 93/42/EEC, with CE Certificate (Class III) and CE Dossier Design certificate.

Safety and product standards: Complies with ISO standards, including ISO 13485 for medical device quality management, ISO 10993 for biological evaluation, ISO 10334 for malleable surgical sutures, and ISO 11607-1 for terminal sterilization packaging. Environmentally compliant, avoiding the use of PVC polymers.

47	Syringe, 0.5 ml, permanently attached needle, sterile, single use	Each	3,080	Disposables
<ul style="list-style-type: none">Product description: Syringe (0.5ml) pre-affixed permanently to needle with protective cap. For accurate administration of low-volume injectables. Sterile, single-use, and disposable.Sterilization method: Ethylene oxide or gamma radiation. Non-toxic and pyrogen-free.Syringe specifications: Capacity: 0.5 ml. Graduated scale: 0.01 ml minor and 0.1 ml major increment lines on barrel. Barrel transparency: Sufficiently transparent for easy volume measurement and air bubble detection. Nozzle: Luer nozzle centrally situated. Material: Medical-grade plastic (Polyethylene (PE), Polypropylene (PP), Polystyrene (PS)).Needle specifications: Material: Stainless steel. Design: Normal and thin-walled. Diameter and length: 27G (approx. 0.4 x 13mm), with external diameter in gauge/millimeters and length preferably in millimeters. Needle tip: Regular bevel, silicone-coated to facilitate insertion. Color coding: Internationally recognized color code for easy identification of external diameter. Cap: Protects needle and preserves sterility. Material: Polypropylene (PP). Supplied with: Manufacturer’s information for use (IFO) either printed on primary packaging or provided on a separate insert. Languages: English and/or Arabic				

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Applications: Intramuscular (IM) injection for children and newborns. Suitable for low-volume injectables, e.g., Vitamin K (2mg/0.2ml solution for newborns, 0.040–0.100 ml volumes). Commonly used for insulin or tuberculin injections.

Safety process:

- Needle is single-use only.
- Use aseptic techniques.

Packaging & Labelling:

- **Primary packaging:** One (1) syringe in individual sterile peel pack made of paper and/or plastic.
- **Secondary packaging:** Protected unit. One (1) box contains 100 blister-packed syringes.

Primary package labelling includes:

- Device identity and intended purpose.
- Manufacturer's product code or reference number.
- Manufacturer identification and address of manufacturing site.
- EC Representative identification.
- Usage, maintenance, and storage instructions.
- Lot/Batch, manufacturing date (MFD), and expiry date (EXP).
- Residual device risks, warnings, limitations, or contraindications.
- ISO 15223 symbols.
- CE mark.
- "Sterile" marking (or equivalent harmonized symbol).
- Sterilization method (or equivalent harmonized symbol).
- "Single use" marking (or equivalent harmonized symbol).
- "Check package integrity before use" or similar warning.
- "Dispose after use" (if space allows).

Secondary package labelling includes:

- Same information as primary packaging.
- Number of units per package.

Regulation & Conformity:

- CE mark as per Medical Device Directive (MDD 93/42/EEC, MDR 2017/745) or FDA 510(k) approved (or equivalent).
- Declaration of Conformity according to ISO 17050.
- ISO 13485 certification.
- Class IIa sterile (MDD 93/42/EEC, MDR 2017/745).

Safety & Product Standards (current versions):

- ISO 11135: Sterilization of health-care products - Ethylene oxide sterilization.
- ISO 11607-1: Packaging for terminally sterilized medical devices - Requirements for materials, sterile barrier, and packaging systems.
- ISO 11607-2: Packaging for terminally sterilized medical devices - Validation requirements for forming, sealing, and assembly processes.
- ISO 6009: Hypodermic needles - Colour coding for identification.
- ISO 7864: Sterile hypodermic needles for single use.
- ISO 80369-1: Small-bore connectors for liquids and gases in healthcare applications - General requirements.
- ISO 80369-7: Connectors for intravascular or hypodermic applications.
- ISO 23908: Sharps injury protection - Requirements and test methods for sharps protection features.
- ISO 9626-1: Stainless steel needle tubing - Requirements and test methods.
- ISO 7886-1: Sterile hypodermic syringes for single use - Syringes for manual use.
- ISO 10993: Biological evaluation of medical devices - Risk management evaluation and testing.

Environmental requirements:

- Compliance with WHO PQS E08.
- Use of alternative polymer materials instead of PVC.
- ISO 14001: Environmental management.

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48	Disinfectant tablet for water containing 1.67 g of sodium dichloroisocyanurate (NaDCC) Sodium dichloroisocyanurate containing 1.67g of NaDCC tablet	Tab	11,200	Disposables
49	Cannula, IV short, 18G, sterile, single use	Each	2,800	Disposables

Product Description: Sterile Intravenous (IV) cannula to be introduced into a peripheral vein for infusing fluids, administering IV drugs, and transfusing blood and blood products (for adult use).

Material:

- **Trocar:** Stainless steel
- **Cannula:** PTFE (Poly Tetra Fluoro Ethylene), FEP (Fluorinated Ethylene Propylene), PUR (Polyurethane). DEHP free

Size: 18G (1.3 x 45 mm) green

Flow Rate: Approx. 80 ml/min

Colour Code/External Diameter: Visible at the base of the cannula.

Design Features:

- Cannula with fine and tapered walls perfectly adjusted to the needle.
- **Distal End:** Straight and tapering.
- **Proximal End:** Base fitted with a luer lock connector and two grasping wings (butterfly) standardized colour code depending on the diameter.
- Fitted with a lateral injection port.
- **Injection Port:** Fitted with a silicone anti-reflux valve cap with colour code and chimney of luer type.
- Protecting cap.
- **Stopper:** Fitted with a hydrophobic membrane with micro-perforations to let air flow while stopping blood (male luer connection).
- **Trocar:** Triple-bevelled.
- **Base:** Transparent female luer base.

Components: Protecting cap, trocar, cannula, stopper, injection port, luer lock (all parts fit together to form a unit).

Sterility: Sterile and single use.

Initial Sterilization Method: Ethylene oxide gas.

Instructions for Use: Sterile IV cannula to be introduced into a peripheral vein for infusing fluids, administering IV drugs, and transfusing blood and blood products.

Safety Process:

- IV cannula is for single use only.
- Rules of asepsis must be followed when inserting the IV cannula.
- The IV cannula should not be left in situ for more than 72 hours.
- It should be removed immediately in case of infection signs.

Supplied With: Manufacturer's instruction for use.

Packaging and Labelling:

- **Primary Packaging:** Unit of use - One (1) IV cannula in an individual sterilized peel pack.
- **Secondary Packaging:** Protected unit - One (1) box of 50 IV cannulas.
- **Symbols Used:** According to ISO 15223, CE mark, and Notified Body number.

Regulation & Conformity Requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE Certificate (Class IIa).

Classification: Class IIa - Medical Device Directive 93/42/EEC.

Safety & Product Standards: Must comply with the following standards:

- ISO 10555-5:2013 Intravascular catheters — Sterile and single-use catheters — Part 5: Over-needle peripheral catheters
- ISO 594-1:1986 (BS EN 20594-1:1994) Conical fittings with a 6% (Luer) taper for syringes, needles, and certain other medical equipment — Part 1: General requirements
- ISO 11607-1:2007 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems, and packaging systems
- ISO 11607-2:2006 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing, and assembly processes

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50	Syringe, Luer lock, 20 ml, sterile, single use	Each	2,800	Disposables
<p>Product Description: Syringe two pieces: barrel with Luer Lock nozzle and piston or three pieces barrel with luer nozzle, piston, and stopper. Without needle.</p> <p>Capacity: 20 ml. Graduated scale on the barrel with 1.0 ml (minor) and 5.0 ml (major) increment lines. Barrel sufficiently transparent to allow easy measurement of the volume contained in the syringe and detection of air bubbles. The Luer Lock nozzle shall be situated centrally.</p> <p>Material: Medical grade plastic; Polyethylene (PE), polypropylene (PP), polystyrene (PS).</p> <p>Sterility: Sterile and disposable. Single use.</p> <p>Sterilization method: Ethylene oxide.</p> <p>Supplied with: Manufacturer's instructions for use may be printed onto the primary packaging or provided on a separate insert. Languages: English, Spanish, and French.</p> <p>Accessories / Spare Parts / Consumables (available but not supplied): N/A</p> <p>Intended use: Syringe is used with an injection needle with compatible luer fitting.</p> <p>Injection safety: The syringe is sterile, ready for immediate use, and is for single use ONLY. Check the integrity of the packaging before opening. Do not use the syringe if the package integrity is compromised.</p> <p>Packaging and Labelling:</p> <ul style="list-style-type: none"> • Primary packaging: One (1) syringe packed in an individual sterilized peel-pack made of paper and/or plastic. • Secondary packaging: One (1) carton box of hundred (100) syringes to blister packs. • Primary package label includes: Device identity and intended purpose, manufacturer's product code or reference number, manufacturer identification, address of the manufacturing site, EC Rep identification, how the device should be used, maintained, and stored, lot/batch and MFD and EXP, any residual device risks, warnings, limitations, or contraindications. • Symbols used: According to ISO 15223, CE mark, the word "sterile" (or equivalent harmonised symbol), sterilization method (or equivalent harmonised symbol), the words "for single use" (or equivalent harmonised symbol), the words "check the package integrity before use" or similar warning, the words "destroy after use" if space allows. • Secondary package label includes the number of units. <p>Regulation and Conformity Requirements: CE mark (conforming to Medical Device Directive MDD 93/42/EEC MDR 2017/745) or FDA 510k approved or equivalent. Declaration of Conformity according to ISO 17050.</p> <p>ISO Classification: Class I - sterile (MDD 93/42/EEC MDR 2017/745).</p> <p>Safety and Product Standards (current versions of the following standards):</p> <ul style="list-style-type: none"> • ISO 11135: Sterilization of health-care products - Ethylene oxide. • ISO 11607-1: Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems, and packaging systems. • ISO 11607-2: Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing, and assembly processes. • ISO 80369-1: Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements. • ISO 80369-7: Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for vascular or hypodermic applications. • ISO 7886-1: Sterile hypodermic syringes for single use - Part 1: Syringes for manual use. • ISO 10993: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process. <p>Product and packaging complies with: WHO PQS E08.</p> <p>Environmental Requirements: Use of other polymer instead of PVC</p>				
51	Needle, Luer, 23G, sterile, single use	Each	2,800	Disposables
<p>Product Description: Needle with base (Luer type fitting) and protective cap for medical use.</p> <p>Material: Needle made of stainless steel; base and protective cap made of plastic.</p> <p>Sterility: Sterile, single use (ethylene oxide sterilization).</p> <p>Size: 23G (0.6 x 25-27 mm).</p>				

Cannula and Tube: Made of stainless steel.

Design Features: Normal or thin-walled; long bevelled (angle $\leq 13^\circ$) or short bevelled (angle between 13° and 19°); silicone-coated to facilitate insertion. The base allows connection to a syringe or other injection devices and is formed by a conical female Luer connection, designed to prevent the needle from rolling on a flat surface, made of polypropylene (PP). The colour code follows an internationally recognized system for easy identification of the hypodermic needle's external diameter. The cap protects the cannula and its bevel, preserving the sterility of the needle, made of polypropylene (PP).

Instructions for Use: For subcutaneous (SC) injection in adults, for intravenous (IV) injection in children, for intramuscular (IM) injection in children, and for intra-arterial use in adults and children.

Safety Process: The needle is for single use only; aseptic techniques must be used when inserting a needle.

Supplied With: Manufacturer's instruction for use.

Packaging and Labelling: Primary packaging consists of one needle packed in an individual sterilized peel pack made of paper and/or plastic. The secondary packaging is a protected unit containing one box of 100 blister-packed needles. The over packaging consists of X protected units packed in rigid packaging with or without plastic film.

Symbols Used: Symbols are according to ISO 15223, with a CE mark and Notified Body number.

Regulation & Conformity Requirements: The product has a CE mark conforming to Medical Device Directive 93/42/EEC and holds a CE Certificate (Class IIa).

Classification: 93/42/EEC Class IIa – CE certificate.

Safety & Product Standards: The product must comply with the following standards: ISO 13485:2003 Medical devices — Quality management systems — Requirements for regulatory purposes; ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process; ISO 11607-1:2007 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems, and packaging systems; ISO 6009:1992 Hypodermic needles for single use — Colour coding for identification; EN 20594-1:1993 Conical fittings with a 6% (Luer) taper for syringes, needles, and certain other medical equipment - Part 1: General requirements (ISO 594-1:1986); ISO 7864:1993 Sterile hypodermic needles for single use.

Environmental Requirements: The use of other polymer instead of PVC is encouraged.

52	Needle, scalp vein, butterfly, 25G, sterile, single use	Each	5,600	Disposables
53	Suture, non-absorbable, DEC3(2-0), 3/8, triangular, 30 mm, sterile	Each	4,032	Disposables

Product description: Non-absorbable synthetic monofilament suture made from nylon, polyester, polyamide, or polypropylene.

- **Thread type:** Non-absorbable synthetic monofilament.
- **Gauge of thread:** Expressed in Decimal gauge (DEC number) and traditional thread numbering; DEC3 (2/0).
- **Length of thread:** Approx. 75 cm.

Needle specifications: **Type:** Curved needle, 3/8 circle. **Point:** Triangular. **Needle length:** Approx. 30 mm.

Shelf life: Minimum of 5 years.

Sterility: Sterile, single-use.

Sterilization method: Ethylene oxide gas or gamma irradiation.

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<p>Instructions for use:</p> <ul style="list-style-type: none">• Suitable for suturing tendons, skin, and face.• The suture length averages 75 cm, with a triangular needle point for easier skin penetration or round for less traumatic tissue insertion.• Made from inert synthetic monofilament, reducing risks of inflammation and rejection compared to traditional silk or linen. <p>Safety process: For single use only. Follow strict aseptic techniques when suturing.</p> <p>Supplied with: Manufacturer’s instructions for use.</p> <p>Packaging & Labelling:</p> <ul style="list-style-type: none">• Primary packaging: One (1) non-absorbable suture in individual sterilized peel pack.• Secondary packaging: One (1) box of 36 non-absorbable sutures.• Labeling: CE mark with Notified Body number, compliant with ISO 15223 symbols. <p>Regulation & Conformity requirements:</p> <ul style="list-style-type: none">• CE mark in line with Medical Device Directive 93/42/EEC.• CE Certificate for Class III or IIb, based on intended use. <p>Safety & Product Standards: Complies with ISO 11607-1:2007, Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems, and packaging systems.</p>				
54	Catheter, urethral, Foley, CH14, sterile	Each	4,200	Disposables
<p>Product Description: Sterile urethral catheter device designed to be introduced into the bladder cavity to drain off urine, instil a liquid, or irrigate the bladder.</p> <p>Material: Natural latex, silicone coated.</p> <p>Size: Diameter is expressed in Charriere French gauge, specifically size CH14. Length is expressed in centimeters, ranging from 30 to 40 cm. The balloon capacity is expressed in milliliters, with a capacity ranging from 5 to 15 ml. This is a straight pointed catheter of Foley type, equipped with a balloon that can be inflated.</p> <p>Design Features: The catheter has a central channel for urinary drainage that ends with a cup connector, allowing connection to a urine bag. It includes a side channel for inflating the balloon, which ends in a non-return valve with Luer tip connection. The colour code and external diameter are visible on the cup connector. The rounded distal end features two facing side windows.</p> <p>Sterilization: Sterile and single use, with the initial sterilization method being ethylene oxide gas.</p> <p>Instructions for Use: The sterile urethral catheter device is intended to be introduced into the bladder cavity to drain urine, instil a liquid, or irrigate the bladder. If lubrication is necessary to facilitate catheter insertion, the substance used must not cause physical or chemical alterations to the catheter; if needed, sterile water may be used. The balloon should be inflated with water or physiological saline. The size has been selected as the most commonly used.</p> <p>Safety Process: The urethral catheter is for single use only. Strict aseptic techniques must be employed when inserting a urethral catheter.</p> <p>Supplied With: Manufacturer's instruction for use.</p> <p>Packaging and Labelling: Primary packaging consists of one Foley catheter in an individual sterilized peel pack. The secondary packaging is a protected unit containing one box of 50 Foley catheters.</p>				

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<p>Symbols Used: Symbols are according to ISO 15223, including the CE mark and Notified Body number.</p> <p>Regulation & Conformity Requirements: The product bears a CE mark conforming to Medical Device Directive 93/42/EEC and holds a CE Certificate (Class IIa).</p> <p>Classification: 93/42/EEC Class IIa – CE certificate.</p> <p>Safety & Product Standards: The product must comply with the following standards: EN 1616:1997 for sterile urethral catheters for single use; ISO 11607-1:2007 for packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems, and packaging systems; ISO 11607-2:2006 for packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing, and assembly processes.</p> <p>Environmental Requirements: The product is latex-free, and it is recommended to use silicone.</p>				
55	Bag, urine, collecting, 2 litres	Each	4,200	Disposables
<p>Product Description: The 2-litre urine collecting bag is used for collecting urine from a patient via a urinary catheter (e.g., Foley), making the bag part of a closed system.</p> <p>Material for Bag: The bag is made of polyvinyl chloride (PVC) or ethylene vinyl acetate (EVA), which is flexible.</p> <p>Tube & Connector/Protective Cap: The tube and protective cap are made of polyvinyl chloride (PVC) and include hanging eyelets and a non-return valve inside the reservoir. The inner side of the bag is sterile. The tube features a universal connector and protective cap to connect to a catheter, with a tube length of approximately 90 cm. It includes a draining valve with a seal cap to maintain sterility.</p> <p>Capacity: The bag has a capacity of 2000 ml and is graduated in increments of 100 ml. It is non-sterile and intended for single use.</p> <p>Instructions for Use: The bag is used for collecting urine from a patient via a urinary catheter, making it part of a closed system. The size has been selected as the most commonly used.</p> <p>Safety Process: The urine-collecting bag is for single use only. Empty used bags should be collected and destroyed through incineration in a controlled environment.</p> <p>Supplied With: Manufacturer's instruction for use.</p> <p>Packaging and Labelling: The product is packaged with ten (10) urine bags in a plastic bag.</p> <p>Symbols Used: Symbols are according to ISO 15223.</p> <p>Regulation & Conformity Requirements: The product bears a CE mark conforming to the Medical Device Directive 93/42/EEC and is self-declared under CE self-declaration. It is ISO 13845:2003 certified.</p> <p>Classification: 93/42/EEC Class I – Self-declaration / CE certificate.</p> <p>Safety & Product Standards: The product must comply with the following standards: BS 7126-2:1989 for urine collection bags, providing methods for determining dimensions; BS 7126-101:1991 for specifications regarding body-worn and non-body-worn bags; ISO 8669-2:1996 for requirements and test methods for urine collection bags.</p> <p>Environmental Requirements: It is recommended to use other polymer materials</p>				

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56	Needle, spinal, 22G, sterile, single use	Each	3,360	Disposables
<p>Product Description: Sterile spinal needle designed for introduction into the sub-arachnoid space to withdraw cerebrospinal fluid (CSF) for diagnostic purposes or for injecting local anaesthetic into the CSF for spinal anaesthesia (surgical purposes). The needle features a Quincke bevel and a transparent hub that allows for easy visualization of cerebrospinal fluid (CSF). It includes a needle core hub with a lock to keep the surface of the needle bevel joint secure. The colour code and external diameter are visible at the base of the spinal needle, with the external diameter expressed in Gauge and mm, and the length expressed in mm.</p> <p>Components: The product consists of a needle, stylet, and sheath.</p> <p>Material: The needle and stylet are made of stainless steel without silicone, while the hub is a clear ridged polycarbonate. The protective sheath is made of plastic.</p> <p>Size Selected: The spinal needle is 22G (0.70 x 90 mm), colored black for spinal anaesthesia in adults. The needle is sterile and for single use only.</p> <p>Initial Sterilisation Method: The initial sterilisation is performed using ethylene oxide gas.</p> <p>Instructions for Use: This sterile spinal needle can be introduced into the sub-arachnoid space to withdraw cerebrospinal fluid (CSF) for diagnostic purposes or for injecting local anaesthetic into the CSF for spinal anaesthesia (surgical purposes). It must be used by qualified personnel only.</p> <p>Safety Process: The spinal needle is for single use only, and strict aseptic techniques must be followed when inserting the spinal needle.</p> <p>Supplied With: Manufacturer's instruction for use.</p> <p>Packaging and Labelling: The primary packaging is a unit of use, containing one (1) spinal needle in an individual sterilised peel pack. The secondary packaging is a protected unit, consisting of one (1) box of 50 spinal needles.</p> <p>Symbols Used: Symbols are according to ISO 15223, including the CE mark with Notified Body number.</p> <p>Regulation & Conformity Requirements: The product bears a CE mark conforming to the Medical Device Directive 93/42/EEC and is certified with a CE Certificate (Class III) + CE Dossier Design certificate.</p> <p>Classification: 93/42/EEC Class III – CE certificate.</p> <p>Safety & Product Standards: The product must comply with the following standards: ISO 11607-1:2007, which outlines requirements for materials, sterile barrier systems, and packaging systems for terminally sterilized medical devices.</p> <p>Environmental Requirements: The product is designed to meet environmental safety standards.</p>				
57	Tape, adhesive, zinc oxide, perforated, 10 cm × 5 m	Each	140	Disposables
<p>Product Description: The product is an adhesive tape made from an aerated and/or perforated textile strip impregnated with adhesive. It boasts high cutaneous tolerance, is non-stretch, and can be torn by hand. The tape is impermeable to water, adheres strongly when applied to the skin, and can be removed without causing significant lesions.</p> <p>Components: The components include a textile strip made of woven acetate taffeta and an adhesive composed of a mixture of rubber resins and lanolin. Traditionally, the adhesive incorporates zinc oxide.</p> <p>Colour: The tape is available in white or flesh-colored options.</p>				

Dimensions: The length is approximately 5 m, and the width is approximately 10 cm. The tape is non-sterile and intended for single use.

Instructions for Use: This adhesive tape is used for fixing dressings and appliances to the skin. Zinc oxide tape is selected for its cost-effectiveness. It is important to note that woven adhesive tape, such as the Micropore type, can be difficult to apply without the use of ether. Quality can be hard to assess, and the adhesive may deteriorate significantly when exposed to heat and dampness. Proper storage conditions should be observed to ensure maximum use and to avoid waste. The tape size has been chosen as the most commonly used for important wound dressing and surgery, specifically 10 cm x 5 m with perforated zinc oxide.

Supplied With: The product includes the manufacturer's instruction for use.

Packaging and Labelling: The primary packaging consists of a unit of use, containing one (1) adhesive tape in a plastic bag. The secondary packaging is a protected unit that includes ten (10) adhesive tapes in a box.

Symbols Used: Symbols are according to ISO 15223, including the CE mark.

Regulation & Conformity Requirements: The product bears a CE mark conforming to the Medical Device Directive 93/42/EEC and is certified under CE self-declaration.

Classification: 93/42/EEC Class I – Self-declaration / CE certified.

58	Blade, scalpel, sterile, single use, no. 22	Each	2,800	Disposables
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Product Description: This is a basic cutting instrument designed for surgical incisions, specifically utilizing a surgical blade (no. 22) for minor surgery with a standard scalpel handle no. 4. The blade is crafted from martensitic stainless steel (quenched magnetic steel) with a hardness rating between 50 HRC and 58 HRC. It is sterile and intended for single use. Each unit is supplied with the manufacturer's instruction for use. The scalpel handle no. 4 is an accessory that is commonly used with this blade.

Instructions for Use: The surgical blade is meant for exposing the vaginal cavity and is strictly single-use. It is crucial to employ aseptic techniques throughout the procedure, including wearing gloves and applying/removing the blade from the scalpel handle using forceps. Used blades should be disposed of in a sealed container to prevent injuries, and after use, these sealed containers must be collected and destroyed through incineration in a controlled environment. Before use, check the integrity of each unit, ensuring that any single-use material supplied in sterile packaging is only utilized if the packaging is undamaged.

Packaging and Labelling: The blades are individually wrapped in a reinforced laminated foil peel pack, maintaining sterility for single use. The labeling includes essential information such as the product name, size, reference number, expiry date, lot number, sterilization method, manufacturer's name and address, and the CE mark, along with the reference number of the notifying body. All labeling must be multilingual, including English and/or Arabic, along with other languages when available. The protective packaging consists of a box containing 100 units, and the labeling is consistent with the unit presentation, indicating the total quantity.

Symbols Used: The product features symbols in accordance with ISO 15223, including the CE mark and Notified Body number.

Regulation & Conformity Requirements: The product is marked with a CE mark, conforming to the Medical Device Directive (MDD) 93/42/EEC, and holds a CE certificate for class IIa with the notifying body number.

Classification: The classification falls under Class IIa as per MDD 93/42/EEC.

Safety & Product Standards: The surgical blades must comply with various standards, including ISO 11607-1:2007 (Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems, and packaging systems), ISO 11607-2:2006 (Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming sealing and assembly processes), ISO 7153-1:1991 (Surgical instruments - Metallic materials - Part 1: Stainless steel), ISO 13402:1995 (Surgical and dental hand instruments

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- Determination of resistance against autoclaving, corrosion, and thermal exposure), and EN 27740/ISO 7740 (Scalpels with detachable blades - Fitting dimensions).

59	Basin, kidney, stainless steel, 825 ml	Each	152	Instruments
<p>Product Description: This kidney-shaped container is designed for the receipt of solid materials, such as dressings, swabs, and soiled tubes, and is commonly used in medical and surgical departments. It is made from austenitic stainless steel with a minimum thickness of 0.8 mm, ensuring durability and a smooth, non-glare surface. The container has an approximate capacity of 825 ml, with dimensions of approximately 250 mm in length, 140 mm in width, and 40 mm in height.</p> <p>Packaging and Labelling: The primary packaging consists of one kidney basin protected by an adhesive plastic film. The label on the primary packaging includes the name and/or trademark of the manufacturer, the manufacturer's product reference, the type of product, and its main characteristics. If the packaging is not transparent, it must display a diagram (preferably actual size) indicating the essential parts of the product and its position within the packaging. Additional information such as the lot number (prefixed by the word "LOT" or an equivalent harmonized symbol), special storage conditions (temperature, pressure, light, humidity, etc.), and handling instructions (if applicable) must also be included. The over packaging contains multiple kidney basins in a box, with labeling consistent with the primary packaging, along with the number of units per box and symbols in accordance with ISO 15223, including the CE mark.</p> <p>Instructions for Use: This container serves as basic equipment for nursing and surgical care, selected for its common size usage. Note that stainless steel containers should not be used to hold chlorine solutions, as this may damage the stainless steel; instead, a plastic container should be utilized. The item must be cleaned and disinfected after each use, and it can be sterilized in a steam sterilizer when necessary.</p> <p>Regulation & Conformity Requirements: The product is marked with a CE mark, conforming to the Medical Device Directive (MDD) 93/42/EEC, and holds a CE self-declaration.</p> <p>Classification: The classification is under Class I according to 93/42/EEC.</p>				
60	Tray, instruments, stainless steel, 22.5 × 12.5 × 5 cm	Each	76	Instruments
<p>Product Description: This seamless rectangular tray with rounded corners is made from austenitic stainless steel, featuring a smooth surface and a cover. The tray measures approximately 225 mm in length, 125 mm in width, and 50 mm in height, with a minimum thickness of 0.8 mm, ensuring durability and suitability for medical use.</p> <p>Packaging and Labelling: The primary packaging consists of one instruments tray with a cover, protected by adhesive plastic film. The label on the primary packaging includes the name and/or trademark of the manufacturer, the manufacturer's product reference, and the type of product along with its main characteristics. If the packaging is not transparent, it must display a diagram (preferably actual size) showing the essential parts of the product and its position within the packaging. Additional information such as the lot number (prefixed by the word "LOT" or an equivalent harmonized symbol), special storage conditions (temperature, pressure, light, humidity, etc.), and handling instructions (if applicable) must also be included. The over packaging contains multiple instruments trays with covers in a box, with labeling consistent with the primary packaging, including the number of units per box and symbols in accordance with ISO 15223, including the CE mark.</p> <p>Instructions for Use: This tray serves as basic equipment for nursing and surgical care, selected for its common size usage. It is important to note that stainless steel containers should not be used to hold chlorine solutions, as this may damage the stainless steel; a plastic container should be utilized instead. The item must be cleaned and disinfected after each use, and it can be sterilized in a steam sterilizer when necessary.</p> <p>Regulation & Conformity Requirements: The product is marked with a CE mark, conforming to the Medical Device Directive (MDD) 93/42/EEC, and holds a CE self-declaration.</p> <p>Classification: The classification is under Class I according to 93/42/EEC.</p>				

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Safety & Product Standards: The product must comply with ISO 7153-1:1991, which outlines the standards for surgical instruments made from metallic materials, specifically stainless steel.				
61	Scissors, Mayo, 14 cm, curved, blunt/blunt	Each	152	Instruments
<p>Product Description: The surgical dissecting scissors, commonly known as Mayo scissors, are designed for non-delicate dissections and for cutting sutures and dressings. Made from martensitic stainless steel (quenched magnetic steel), the composition includes 0.40% carbon and 14% chromium, ensuring durability and sharpness. These scissors feature thin, curved blades with blunt ends for safe and effective cutting, measuring approximately 140 mm in length.</p> <p>Instructions for Use: These scissors must be cleaned and disinfected after each use and sterilized in a steam sterilizer to maintain hygiene and safety.</p> <p>Packaging and Labelling: The scissors are individually presented in protective packaging. The packaging clearly displays the designation of the instrument along with the name and address of the supplier (manufacturer). Additionally, symbols in accordance with ISO 15223, including the CE mark, are included.</p> <p>Regulation & Conformity Requirements: The product is marked with a CE mark, conforming to the Medical Device Directive (MDD) 93/42/EEC, and holds a CE self-declaration.</p> <p>Classification: The classification is under Class I according to 93/42/EEC.</p> <p>Safety & Product Standards: The scissors must comply with several standards, including ISO 10993-1:2009 for biological evaluation of medical devices, ISO 7153-1:1991 for surgical instruments made from metallic materials, ISO 13402:1995 for the determination of resistance against autoclaving corrosion and thermal exposure, ISO 7741:1986 for general requirements and test methods for surgical scissors and shears, and ISO 17664:2004, which provides information for the processing of resterilizable medical devices.</p>				
62	Scissors, gynaecological, 20 cm, curved, blunt/blunt	Each	180	Instruments
<p>Product Description: These surgical scissors are specifically designed for cutting the perineal skin and tissue during an episiotomy, facilitating the passage of the fetal head. They can also be used for the decapitation of a dead fetus. Constructed from martensitic stainless steel (quenched magnetic steel) with a composition of 0.40% carbon and 14% chromium, the scissors feature curved blades with blunt ends for safe and effective cutting, measuring approximately 200 mm in length.</p> <p>Instructions for Use: The scissors should be cleaned and disinfected after each use and sterilized in a steam sterilizer to ensure hygiene and patient safety.</p> <p>Packaging and Labelling: The primary packaging consists of one pair of scissors enclosed in a plastic bag. The labelling on the primary packaging includes the manufacturer's name and/or trademark, the manufacturer's product reference, and the type of product along with its main characteristics. If the packaging is not transparent, it will feature a diagram showing the essential parts of the product and its position within the packaging. Additional information such as the lot number (prefixed by the word "LOT," if applicable), storage conditions (temperature, pressure, light, humidity), and handling instructions are also included. The secondary packaging protects the unit, containing ten (10) scissors in a box, with labelling that mirrors the primary packaging. Overpackaging is also employed to ensure safe transport.</p> <p>Regulation & Conformity Requirements: The scissors bear a CE mark conforming to the Medical Device Directive (MDD) 93/42/EEC and are certified under ISO 13845:2003.</p> <p>Classification: The classification falls under Class I according to MDD 93/42/EEC.</p> <p>Safety & Product Standards: These scissors must comply with several standards, including ISO 10993-1:2009 for the biological evaluation of medical devices, ISO 7153-1:1991 for metallic materials in surgical instruments, ISO 13402:1995 for determining resistance against</p>				

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autoclaving corrosion and thermal exposure, ISO 7741:1986 for general requirements and test methods for surgical scissors and shears, and ISO 17664:2004, which provides information for the sterilization of medical devices.

63	Timer, 60 minutes, mechanical	Each	76	Instruments
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Product Description: This mechanical spring-driven countdown timer is designed for professional use, featuring an easy-to-read ring or dial graduated from 0 to 60 minutes in 5 and 1-minute intervals. The timer is set and started by rotating the dial or part of the housing, ensuring intuitive operation. It includes a loud, long ring alert that sounds at the end of the timer period. Constructed with a robust housing made from shock-resistant materials, the timer features internal gears made of stainless steel or ABS, and its smooth finishing allows for easy cleaning. It is stable when set up on a workbench or table and is compact enough to fit in a pocket, making it easy to transport. The timer is available in a round, conical, or square design.

Instructions for Use: This timer is used for various techniques to regulate timing and is suitable for facilities with limited access to replacement batteries, such as laboratory networks at levels 1-II.

Packaging and Labelling: The primary packaging includes one (1) mechanical timer with a 60-minute countdown.

Regulation & Conformity Requirements: The timer complies with Directive 2004/22/EC and is supplied with a CE certificate.

Safety & Product Standards: It adheres to the ISO 9001:2008 quality management standards, ensuring reliable performance and safety.

64	Drum, sterilizing, diameter 165 mm	Each	152	Instruments
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Product Description: This cylindrical container is designed for sterilizing dressing materials, such as gauze, compresses, or cotton, in a steam sterilizer (autoclave), while also maintaining their sterility for medical activities like dressing or injections. The container features an effective closing lid with a clip lock, a carrying handle, and an air vent system that allows steam to circulate freely during the sterilization cycle. The lateral air vents system is preferred for efficiency and ease of operation, and vents can be manually closed after sterilization. Constructed from austenitic stainless steel with a smooth surface, the container has a composition of approximately 8 to 10% nickel and 18 to 20% chromium. It has an external diameter of approximately 150 to 165 mm, a height of about 100 to 120 mm, and a thickness of approximately 0.6 to 0.7 mm.

Instructions for Use: The cylindrical container is used to sterilize dressing materials in a steam sterilizer and to keep them sterile for medical applications. During the sterilization process, the air vents should be open. After the sterilization cycle is complete, the air vents must be closed immediately upon removing the drum from the autoclave. It is important not to overfill the drum with compresses or cotton, as pressurized steam will not penetrate the center effectively, preventing proper sterilization. The container's size has been optimized for common use, considering various types of steam sterilizers and their internal dimensions to enhance sterilization efficacy.

Packaging and Labelling: The product is packaged as one (1) drum in a plastic bag, accompanied by a box that includes the manufacturer's instructions for use in three languages: English, French, and Spanish. The packaging features symbols in accordance with ISO 15223 and includes a CE mark.

Regulation & Conformity Requirements: The container complies with the CE mark and conforms to the Medical Device Directive 93/42/EEC, classified as Class I under this directive.

65	Drum, sterilizing, diameter 260 mm	Each	152	Instruments
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Product Description: This cylindrical container is designed for sterilizing dressing materials, surgical instruments, and other reusable medical devices in a steam sterilizer (autoclave). It ensures that these items remain sterile for medical activities. The container features an effective closing lid with a clip lock, a carrying handle, and an air vent system that allows steam to circulate freely during the sterilization cycle. The vents can be manually closed after sterilization, and the air vent system's opening and closure mechanism is efficient and easy to operate. A lateral air vent system is preferred over top and bottom vents for optimal functionality. Constructed from austenitic stainless steel with a smooth surface, the container has a composition of approximately 8 to 10% nickel and 18 to 20% chromium. It has an external diameter of approximately 240 to 260 mm, a height of about 160 to 170 mm, and a thickness of approximately 0.6 to 0.7 mm.

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Instructions for Use: This cylindrical container is utilized to sterilize dressing materials, surgical instruments, and other reusable medical devices in a steam sterilizer. During the sterilization process, the air vents should remain open. Once the sterilization cycle is complete, close the air vents immediately after removing the drum from the autoclave. It is important not to overfill the drum with compresses or cotton, as pressurized steam may not penetrate the center effectively, preventing proper sterilization. The container's size has been chosen based on common usage, considering various types of steam sterilizers and their internal dimensions to enhance sterilization activities.

Packaging and Labelling: The product is packaged as one (1) drum in a plastic bag, accompanied by a box that includes the manufacturer's instructions for use in three languages: English and/or Arabic. The packaging features symbols in accordance with ISO 15223 and includes a CE mark.

Regulation & Conformity Requirements: The container complies with the CE mark and conforms to the Medical Device Directive 93/42/EEC, classified as Class I under this directive. It also meets the safety and product standards as per EN 10088-1 for stainless steels.

66	Drum, sterilizing, diameter 290 mm	Each	152	Instruments
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Product Description: This cylindrical container is specifically designed for use in a steam sterilizer (autoclave) to sterilize dressing materials, surgical instruments, and other reusable medical devices, ensuring they remain sterile for medical purposes. It features an effective closing lid with a clip lock, a convenient carrying handle, and an air vent system that facilitates free circulation of steam during the sterilization cycle. The vents are manually closed after sterilization, and the air vent system's opening and closure mechanism is both efficient and easy to operate, with a lateral air vent system preferred over top and bottom options. Constructed from austenitic stainless steel with a smooth surface, the container's composition includes approximately 8 to 10% nickel and 18 to 20% chromium. It has an external diameter of approximately 280 to 290 mm, a height of about 160 to 180 mm, and a thickness of approximately 0.6 to 0.7 mm.

Instructions for Use: This cylindrical container is utilized to sterilize dressing materials, surgical instruments, and other reusable medical devices in a steam sterilizer (autoclave), keeping them sterile for medical activities. During the sterilization process, the air vents should remain open. Once the sterilization cycle is complete, it is crucial to close the air vents immediately after removing the drum from the autoclave. Avoid overfilling the drum with compresses or cotton, as the pressurized steam may not penetrate the center effectively, hindering proper sterilization. The container's size has been selected based on common usage, considering various types of steam sterilizers and their internal dimensions to optimize sterilization activities.

Packaging and Labelling: The product is packaged as one (1) drum in a plastic bag, along with a box that contains the manufacturer's instructions for use in three languages: English, French, and Spanish. The packaging includes symbols in accordance with ISO 15223 and displays a CE mark.

Regulation & Conformity Requirements: The container complies with the CE mark and conforms to the Medical Device Directive 93/42/EEC, classified as Class I under this directive. It must also meet safety and product standards as specified in EN 10088-1 for stainless steels.

67	Flashlight, frontal, LED, battery operated, including batteries	Each	76	Instruments
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High quality ultra bright white light frontal lamp with 7 LED.

- High intensity and durable lifetime.
- High impact plastic handle.
- Waterproof.
- The frontal lamp can be attached to a forehead of a user by head straps threaded through strap holders on the rear of the frontal lamp.
- Handy switch point for easier operation.
- Tilting lamp.
- With adjustable head straps.
- Battery operated with AA batteries.
- With adapter for alternative use with electrical socket.

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- Operation life span: minimum 100,000 hours.

Supplied with: 1 pair of head straps - 1 adapter - AA batteries required to operate the frontal lamp - CE mark.

68	Scissors, Mayo, 17 cm, curved, blunt/blunt	Each	56	Instruments
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Product Description: The Mayo surgical dissecting scissors are designed for non-delicate dissections and are effective for cutting sutures and dressings. Constructed from martensitic stainless steel (quenched magnetic steel), the scissors have a composition of 0.40% carbon and 14% chromium. These instruments utilize a shearing action to cut, featuring thin, curved blades with blunt ends, and they measure approximately 170 mm in length.

Instructions for Use: These surgical dissecting scissors are intended for non-delicate dissections and for cutting sutures and dressings. It is essential that the scissors are cleaned, disinfected after each use, and sterilized in a steam sterilizer to maintain hygiene and safety.

Packaging and Labelling: The scissors are individually presented in protective packaging. The packaging includes essential information, such as the designation of the instrument and the name and address of the supplier (manufacturer). It also displays symbols in accordance with ISO 15223, including the CE mark.

Regulation & Conformity Requirements: The product bears a CE mark, conforming to the Medical Device Directive 93/42/EEC, and is classified as Class I under this directive. It is certified under ISO 13845:2003 and must comply with several safety and product standards, including ISO 13485:2003 for medical devices quality management systems, ISO 10993-1:2009 for biological evaluation of medical devices, ISO 7153-1:1991 for metallic materials in surgical instruments, ISO 13402:1995 for resistance to autoclaving, ISO 7741:1986 for general requirements of surgical scissors and shears, and ISO 17664:2004 for sterilization information for resterilizable medical devices.

69	Needle holder, Mayo-Hegar, 18 cm, straight	Each	56	Instruments
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Product Description: The Mayo-Hegar needle holder is specifically designed for holding tiny suture needles securely while stitching, making it an essential tool for general surgery. Crafted from martensitic stainless steel (quenched magnetic steel), the composition includes 0.16% to 0.25% carbon and 12% to 14% chromium. The instrument features a straight design with a ratchet mechanism that allows for varying degrees of grip tightness, ensuring the needle is held firmly in place. A well-defined longitudinal groove is incorporated to prevent any deterioration of the needle during use. The needle holder measures approximately 180 mm in length.

Instructions for Use: This needle holder is utilized for gripping suture needles while stitching in general surgical procedures. It is crucial that the instrument is cleaned and disinfected after each use, and sterilized in a steam sterilizer to maintain safety and hygiene.

Packaging and Labelling: The needle holder is supplied in a plastic bag, ensuring protection during storage and transport. It also includes symbols in accordance with ISO 15223, including the CE mark.

Regulation & Conformity Requirements: The product carries a CE mark that conforms to the Medical Device Directive 93/42/EEC and is classified as Class I under this directive. It is certified under ISO 13845:2003, ensuring compliance with established safety and product standards. It must also adhere to the standards outlined in ISO 7153-1:1991 for surgical instruments.

70	Retractor, vaginal, Doyen, 8.5 × 4.5 cm	Each	56	Instruments
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Product description: Vaginal retractor (also called vaginal speculum) 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.

Material: Austenitic stainless steel (non-quenched non-magnetic steel) composition: 18% to 20% chromium; 8 to 10% nickel. Weight which fits on the shank of the blade. Weight should be soldered/welded rather than screwed. Lateral edges must be blunt.

Blade: medium hollow shaped.

Blade length: approx. 85mm.

Blade width: approx. 45mm.

Length: approx. 240mm.

Supplied with: Manufacturers instruction for use.

Instructions for use: To expose the vaginal cavity. This item must be cleaned disinfected after each use and sterilised in a steam steriliser.

Packaging & Labelling: Unit presentation: individually in protective packaging. The following should appear on the packaging: - Designation of the instrument. - Name and address and supplier (manufacturer).

Symbols used according ISO 15223: CE mark.

Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2003 certified.

Classification: Class I (MDD 93/42/EEC).

Safety & product Standards: Must comply with following standards ISO 7153-1:1991 Surgical instruments -- Metallic materials -- Part 1: Stainless steel. ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving corrosion and thermal exposure. ISO 17664:2004 Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices.

71	Speculum, vaginal, Graves, 75 × 20 mm	Each	28	Instruments
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Product description: Vaginal speculum Graves for examining the walls of the vagina and cervix of the uterus.

Material: Austenitic steel (non-quenched non-magnetic steel). Double beaked vaginal speculum self-retaining.

Blade length: approximately 75mm.

Blade width: approximately 20mm.

Supplied with: Manufacturers instruction for use.

Instructions for use: To examine 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: One (1) speculum in a plastic bag.

Symbols used according ISO 15223: CE mark.

Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13485:2003 certified.

Classification: Class I-Medical Device Directive 93/42/EEC.

Safety & product Standards: Must comply with the following standards: ISO 7153-1:1991, ISO 7151:1988, ISO 17664:2004, ISO 13402:1995.

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72	Speculum, vaginal, Graves, 95 × 35 mm	Each	28	Instruments
<p>Product description: Vaginal speculum Graves for examining the walls of the vagina and cervix of the uterus.</p> <p>Material: Austenitic steel (non-quenched non-magnetic steel). Double beaked vaginal speculum self-retaining.</p> <p>Blade length: approximately 95mm.</p> <p>Blade width: approximately 35mm.</p> <p>Supplied with: Manufacturers instruction for use.</p> <p>Instructions for use: To examine 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.</p> <p>Packaging & Labelling: One (1) speculum in a plastic bag.</p> <p>Symbols used according ISO 15223: CE mark.</p> <p>Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13485:2003 certified.</p> <p>Classification: Class I-Medical Device Directive 93/42/EEC.</p> <p>Safety & product Standards: Must comply with the following standards: ISO 7153-1:1991, ISO 7151:1988, ISO 17664:2004, ISO 13402:1995.</p>				
73	Speculum, vaginal, Graves, 115 × 35 mm	Each	28	Instruments
<p>Product description: Vaginal speculum Graves for examining the walls of the vagina and cervix of the uterus.</p> <p>Material: Austenitic steel (non-quenched non-magnetic steel). Double beaked vaginal speculum self-retaining.</p> <p>Blade length: approximately 115mm.</p> <p>Blade width: approximately 35mm.</p> <p>Supplied with: Manufacturers instruction for use.</p> <p>Instructions for use: To examine 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.</p> <p>Packaging & Labelling: One (1) speculum in a plastic bag.</p> <p>Symbols used according ISO 15223: CE mark.</p> <p>Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13485:2003 certified.</p> <p>Classification: Class I-Medical Device Directive 93/42/EEC.</p> <p>Safety & product Standards: Must comply with the following standards: ISO 7153-1:1991, ISO 7151:1988, ISO 17664:2004, ISO 13402:1995.</p>				
74	Forceps, dressing, Cheron, 25 cm	Each	112	Instruments
<p>Product description: Vaginal dressing forceps Cheron for dressing/swabbing of vagina in preparation for surgical intervention. Also used as serving forceps (used with jar for forceps).</p> <p>Material: Martensitic stainless steel (quenched magnetic steel). Composition: 0.20% carbon; 13% chromium.</p> <p>Spring-type: Flexible arms.</p> <p>Variable setting of ratchet: Lockable.</p> <p>Adjustment of jaws: Highly impact resistant.</p> <p>Length: approx. 250 mm.</p> <p>Supplied with: Manufacturers instruction for use.</p> <p>Instructions for use: Used for dressing/swabbing of vagina in preparation for surgical intervention. Also used as serving forceps (used with jar for forceps). This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser.</p> <p>Packaging & Labelling: One (1) forceps in a plastic bag.</p> <p>Symbols used according ISO 15223: CE mark.</p>				

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Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2003 certified.

Classification: Class I-Medical Device Directive 93/42/EEC.

Safety & product Standards: Must comply with the following standards: ISO 7153-1:1991, ISO 7151:1988, ISO 17664:2004, ISO 13402:1995.

75	Tray, instruments, stainless steel, 32 × 20 × 8 cm, with cover	Each	28	Instruments
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Product description: Seamless tray with cover rectangular with rounded corners stainless steel smooth surface.

Material: Austenitic stainless steel.

Length: approximately 320 mm.

Width: approximately 200 mm.

Height: approximately 80 mm.

Packaging and labelling:

Primary packaging: Unit of use. One (1) instruments tray with cover protected by adhesive plastic film.

Labelling on the primary packaging: Name and/or trademark of the manufacturer. Manufacturers product reference. Type of product and main characteristics. If the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging. Lot number prefixed by the word LOT (or equivalent harmonised symbol) if applicable. Information for particular storage conditions (temperature, pressure, light, humidity, etc.) as appropriate (or equivalent harmonised symbol). Information for handling if applicable (or equivalent harmonised symbol).

Over packaging: Packaging unit X instruments trays with cover in a box.

Labelling on the packaging unit: Labelling to be the same as primary packaging.

Extra information required: Number of units per box.

Symbols used according ISO 15223: CE Mark.

Instructions for use: Basic equipment for nursing and surgical care. The size has been chosen as being the most commonly used. Note: Do not use a stainless steel container to hold a chlorine solution as this may damage the stainless steel; use a plastic container. This item must be cleaned, disinfected after each use. It can be sterilized in a steam sterilizer when necessary.

Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2003 certified.

Classification: 93/42/EEC Class I – Self declaration / CE cert.

Safety & product Standards: Must comply with following standards: ISO 7153-1:1991 Surgical instruments -- Metallic materials -- Part 1: Stainless steel.

76	Clamp, towel, Backhaus, 120 mm	Each	112	Instruments
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Product description: Towel clamp Backhaus for attaching towels around the surgical incision either with or without piercing the skin.

Material: Martensitic stainless steel (quenched magnetic steel).

Spring-type: Hard ratchet fine single tooth in each jaw.

Lockable.

Length: approx. 120 mm.

Instructions for use: Used to attach towels around the surgical field with or without piercing the skin. This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser.

Supplied with: Manufacturers instruction for use.

Packaging and labelling:

Primary packaging: Unit of use. One (1) clamp in a plastic bag.

Labelling on the primary packaging: Name and/or trademark and address of the manufacturer. Manufacturers product reference. Type of product and main characteristics. Lot number prefixed by the word LOT (or equivalent harmonised symbol if applicable). Information

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<p>for particular storage conditions (temperature, pressure, light, humidity, etc.) as appropriate (or equivalent harmonised symbol). CE mark.</p> <p>Secondary packaging: Protected unit. Four (4) Backhaus towel clamps in a box.</p> <p>Labelling on the secondary packaging: Labelling to be the same as primary packaging.</p> <p>Extra information required: Number of units per secondary packaging.</p> <p>Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13485:2003 certified.</p> <p>Classification: Class I-Medical Device Directive 93/42/EEC.</p> <p>Safety & product Standards: ISO 13485:2003 Quality management systems -- Requirements for regulatory purposes. ISO 14971:2007 Medical Devices - Application of risk management to medical devices. ISO 7153-1:1991/Amd1:1999 Surgical instruments - Metallic material – Part 1 Stainless Steel. 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 17664:2004 Sterilization of medical devices -- Information to be provided by the manufacturer for the processing of re-sterilizable medical devices.</p> <p>Environmental requirements: Not use PVC polyme</p>				
77	Forceps, artery, Kelly, 14 cm, curved	Each	280	Instruments
<p>Product description: Used for haemostasis inserting drains and for holding a compress used as a tampon.</p> <p>Material: Martensitic stainless steel (quenched magnetic steel) composition: 0.20% carbon; 13% chromium.</p> <p>Curved.</p> <p>Flexible arms.</p> <p>Variable settings of the ratchet lockable.</p> <p>Adjustment of the jaws.</p> <p>Length: approx. 140 mm.</p> <p>Supplied with: Manufacturers instruction for use.</p> <p>Instructions for use: Hemostatic forceps Kelly used for haemostasis inserting drains and for holding a compress used as a tampon. This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser.</p> <p>Packaging & Labelling: One (1) forceps in a plastic bag.</p> <p>Symbols used according ISO 15223 CE mark.</p> <p>Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13485:2003 certified.</p> <p>Classification: Class I-Medical Device Directive 93/42/EEC.</p> <p>Safety & product Standards: Must comply with the following standards: ISO 7153-1:1991 ISO 7151:1988 ISO 17664:2004 ISO 13402:1995.</p>				
78	Forceps, artery, Halsted-Mosquito, 12.5 cm, curved	Each	168	Instruments
<p>Product description: Hemostatic forceps Halsted-Mosquito used for haemostasis. Not intended for nursing care.</p> <p>Curved and slim.</p> <p>Material: Martensitic stainless steel (quenched magnetic steel) composition: 0.20% carbon; 13% chromium.</p> <p>Spring-type.</p> <p>Atraumatic jaws.</p> <p>Flexible arms.</p> <p>Variable settings of the ratchet lockable.</p> <p>Without teeth.</p> <p>Highly impact resistant.</p> <p>Length: approx. 125 mm.</p>				

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Supplied with: Manufacturers instruction for use.

Instructions for use: Hemostatic forceps Halsted-Mosquito used for haemostasis. Not intended for nursing care. 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.

Symbols used according ISO 15223 CE mark.

Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2003 certified.

Classification: Class I-Medical Device Directive 93/42/EEC.

Safety & product Standards: Must comply with the following standards: ISO 7153-1:1991 ISO 7151:1988 ISO 17664:2004 ISO 13402:1995.

79	Forceps, artery, Kocher, 14 cm, straight	Each	56	Instruments
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Product description: Haemostatic forceps Kocher straight used for multi-purpose in surgery: haemostasis, dissection, gripping of vessels, inserting drains, and for holding a compress used as a tampon. May be used for nursing care outside the operation theatre.

Material: Martensitic stainless steel (quenched magnetic steel) composition: 0.20% carbon; 13% chromium.

Slightly springy.

Flexible arms.

Variable setting of the ratchet.

Adjustment of the jaws.

1x2 teeth.

Heavily serrated jaws.

Box lock.

Highly impact resistant.

Length: approx. 140 mm.

Supplied with: Manufacturers instruction for use.

Instructions for use: Hemostatic forceps Kocher used for general use: haemostasis, gripping, dissection, tampon holder. This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser.

Packaging & Labelling: One (1) forceps in a plastic bag.

Symbols used according ISO 15223 CE mark.

Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2003 certified.

Classification: Class I-Medical Device Directive 93/42/EEC.

Safety & product Standards: Must comply with the following standards: ISO 7153-1:1991 ISO 7151:1988 ISO 17664:2004.

80	Forceps, artery, Rochester-Pean, 20 cm, curved	Each	56	Instruments
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Product Description: Hemostatic forceps Rochester-Pean curved for haemostasis, gripping, dissection, and tampon holder. Curved.

Material: Martensitic stainless steel (quenched magnetic steel) composition: 0.20% carbon; 13% chromium.

Springy.

<p>Locking variable setting of ratchet lockable.</p> <p>Serrated jaws.</p> <p>Non-traumatic jaws.</p> <p>Adjustment of jaws.</p> <p>Without teeth.</p> <p>Highly impact resistant.</p> <p>Length: approx. 200 mm.</p> <p>Supplied with: Manufacturers instruction for use.</p> <p>Instructions for use: Used for haemostasis, gripping, dissection, and tampon holder. This item must be cleaned and disinfected after each use and sterilised in a steam steriliser.</p> <p>Packaging & Labelling: One (1) forceps in a plastic bag.</p> <p>Symbols used according to ISO 15223.</p> <p>CE mark.</p> <p>Regulation & Conformity Requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2003 certified.</p> <p>Classification: Class I - Medical Device Directive 93/42/EEC.</p> <p>Safety & Product Standards: Must comply with the following standards: ISO 7153-1:1991, ISO 7151:1988, ISO 17664:2004, ISO 13402:1995</p>				
81	Forceps, artery, Rochester-Pean, 24 cm, curved	Each	56	Instruments
<p>Product Description: Hemostatic curved Rochester-Pean forceps for haemostasis, gripping, dissection, and tampon holding. Curved.</p> <p>Material: Martensitic stainless steel (quenched magnetic steel) composition: 0.20% carbon; 13% chromium.</p> <p>Springy.</p> <p>Variable setting of ratchet lockable.</p> <p>Serrated jaws.</p> <p>Non-traumatic jaws.</p> <p>Adjustment of jaws.</p> <p>Without teeth.</p> <p>Highly impact resistant.</p> <p>Length: 240 mm (+/- 5%).</p> <p>Supplied with: Manufacturers instructions for use, cleaning, disinfection, and sterilization in English and/or Arabic.</p> <p>Intended use: Used for haemostasis, gripping, dissection, and tampon holding. This item must be cleaned and disinfected after each use and sterilised in a steam steriliser.</p> <p>Packaging and Labelling: One (1) unit in protective packaging with a label that includes:</p> <ul style="list-style-type: none">• Device identity and intended purpose.				

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- Manufacturers product code or reference number.
- Manufacturer identification.
- Address of the manufacturing site.
- EC Rep identification.
- How the device should be used, maintained, and stored.
- Lot/Batch and MFD.
- Any residual device risks, warnings, limitations, or contraindications.
- Symbols used according to ISO 15223.
- CE mark.

Regulation and Conformity Requirements: CE mark (conforming to Medical Device Directive MDD 93/42/EEC MDR 2017/745) or FDA 510k approved or equivalent. Declaration of Conformity according to ISO 17050. ISO 13485.

Classification: Class I (MDD 93/42/EEC), Class I - reusable surgical instrument (MDR 2017/745).

Safety and Product Standards (current versions of the following standards):

- ISO 7153-1: Surgical instruments - Materials - Part 1: Metals.
- ISO 7151: Surgical instruments - Non-cutting articulated instruments - General requirements and test methods.
- ISO 17664: Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices.
- ISO 13402: Surgical and dental hand instruments - Determination of resistance against autoclaving, corrosion, and thermal exposure.

82	Forceps, artery, Mixer, 23 cm	Each	28	Instruments
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Product Description: Delicate threading forceps Mixer for dissecting and for passing a thread around a vein or artery.

Material: Martensitic stainless steel (quenched magnetic steel) composition: 0.20% carbon; 13% chromium.

Springy.

Flexible ratchet lockable.

Jaws which grip the thread well.

Highly impact resistant.

Length: approx. 230 mm.

Supplied with: Manufacturers instruction for use.

Instructions for use: For dissecting and for passing a thread around a vein or artery. This item must be cleaned and disinfected after each use and sterilised in a steam steriliser.

Packaging & Labelling: One (1) forceps in a plastic bag.

Symbols used according to ISO 15223.

CE mark.

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Regulation & Conformity Requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration. ISO 13845:2003 certified.

Classification: Class I - Medical Device Directive 93/42/EEC.

Safety & Product Standards: Must comply with the following standards: ISO 13485: 2003, ISO 10993-1:2009, BS 5194-3:1985, ISO 7153-1:1991, ISO 7151:1988, ISO 17664:2004, ISO 13402:1995.

83	Forceps, dressing, standard, 145 mm, straight	Each	28	Instruments
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Product Description: Dissecting forceps used in surgery for dissecting and gripping tissues as well as coagulation of vessels. Also used in nursing for making a compress into a tampon for sponging. Used to change dressings. Dissecting forceps are spring-type, straight, without teeth, with flexible arms and serrated jaws, providing good jaw grips.

Material: Martensitic steel (quenched magnetic steel).

Highly impact resistant.

Length: approx. 145 mm.

Instructions for use: Used to hold tissues during dissections and for coagulation of vessels. Used in surgery and nursing. Used to change dressings. This item must be cleaned and disinfected after each use and sterilised in a steam steriliser.

Supplied with: Manufacturers instruction for use.

Packaging and Labelling: One (1) forceps in a plastic bag.

Labelling on the primary packaging: Name and/or trademark and address of the manufacturer, manufacturers product reference, lot number prefixed by the word LOT (or equivalent harmonised symbol if applicable), symbols used according to ISO 15223 and EN 980, CE mark.

Regulation & Conformity Requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration, ISO 13485:2003 certified.

Classification: Class I - Medical Device Directive 93/42/EEC.

Safety & Product Standards: Must comply with the following standards: ISO 13485:2003, ISO 14971:2007, ISO 7153-1:1991/Amd1:1999, ISO 7151:1988, ISO 13402:1995, ISO 17664:2004.

Environmental Requirements: Not use PVC polymer.

84	Forceps, dressing, standard, 250 mm, straight	Each	28	Instruments
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Product Description: Dissecting forceps used in surgery for dissecting and gripping tissues as well as coagulation of vessels. Also used in nursing for making a compress into a tampon for sponging. Used to change dressings. Dissecting forceps are spring-type, straight, without teeth, with flexible arms and serrated jaws, providing good jaw grips.

Material: Martensitic steel (quenched magnetic steel).

Highly impact resistant.

Length: approx. 250 mm.

Instructions for Use: Used to hold tissues during dissections and for coagulation of vessels. Used in surgery and nursing. Used to change dressings. This item must be cleaned and disinfected after each use and sterilised in a steam steriliser.

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Supplied with: Manufacturers instruction for use.

Packaging and Labelling: One (1) forceps in a plastic bag.

Labelling on the Primary Packaging: Name and/or trademark and address of the manufacturer, manufacturers product reference, lot number prefixed by the word LOT (or equivalent harmonised symbol if applicable), symbols used according to ISO 15223 and EN 980, CE mark.

Regulation & Conformity Requirements: CE mark conforming to Medical Device Directive 93/42/EEC CE self-declaration, ISO 13485:2003 certified.

Classification: Class I - Medical Device Directive 93/42/EEC.

Safety & Product Standards: Must comply with the following standards: ISO 13485:2003, ISO 14971:2007, ISO 7153-1:1991/Amd1:1999, ISO 7151:1988, ISO 13402:1995, ISO 17664:2004.

Environmental Requirements: Not use PVC polymer.

85	Forceps, intestinal clamp, Doyen, 23 cm, curved	Each	28	Instruments
<p>Product Description: Intestinal clamp Doyen, curved, used for transverse non-crushing occlusion of a section of intestine while suturing an anastomosis.</p> <p>Material: Martensitic stainless steel (quenched magnetic steel) composition: 0.20% carbon; 13% chromium.</p> <p>Curved.</p> <p>Jaws: Very springy and soft.</p> <p>Features: Non-traumatic occlusion; the form and mechanical action permit precise closing; multiple ratchet; box lock.</p> <p>Highly impact resistant.</p> <p>Length: approx. 230 mm.</p> <p>Supplied with: Manufacturers instruction for use.</p> <p>Instructions for Use: Used for transverse non-crushing occlusion of a section of intestine while suturing an anastomosis. This item must be cleaned and disinfected after each use and sterilised in a steam steriliser.</p> <p>Packaging & Labelling: One (1) forceps in a plastic bag.</p> <p>Symbols Used: According to ISO 15223.</p> <p>CE Mark: Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC, CE self-declaration, ISO 13845:2003 certified.</p> <p>Classification: Class I - Medical Device Directive 93/42/EEC.</p> <p>Safety & Product Standards: Must comply with the following standards: ISO 7153-1:1991, ISO 7151:1988.</p>				

86	Forceps, uterine, Phaneuf, 21.5 cm, curved	Each	56	Instruments
<p>Product Description: Hemostatic forceps for haemostasis of the arteries in the uterine, curved.</p> <p>Material: Martensitic stainless steel (quenched magnetic steel) composition: from 0.16% to 0.25% carbon and from 12% to 14% chromium.</p> <p>Double curved.</p>				

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Features: Slightly springy; flexible arms; variable setting of ratchet (lockable); adjustment of the jaws; curved angled on flat forceps with 1 x 2 teeth.

Length: 215 mm.

Supplied with: Manufacturers instruction for use.

Instructions for Use: For haemostasis of the arteries in the uterine. This item must be cleaned and disinfected after each use and sterilised in a steam steriliser.

Packaging & Labelling: One (1) forceps in a plastic bag.

Symbols Used: According to ISO 15223.

CE Mark: Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC, CE self-declaration, ISO 13845:2003 certified.

Classification: Class I - Medical Device Directive 93/42/EEC.

Safety & Product Standards: Must comply with the following standards: ISO 7153-1:1991, ISO 7151:1988.

87	Forceps, uterine, Duplay, 28 cm, curved	Each	28	Instruments
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Product Description: Uterine traction/tenaculum/vulsellum forceps Duplay for gripping and immobilisation of thick tissue (uterine traction forceps).

Material: Martensitic stainless steel (quenched magnetic steel) composition: 0.20% carbon; 13% chromium.

Double curved.

Features: Hard ratchet (lockable); highly impact resistant.

Length: Approx. 280 mm.

Supplied with: Manufacturers instruction for use.

Instructions for Use: For gripping and immobilisation of thick tissue (uterine traction forceps). This item must be cleaned and disinfected after each use and sterilised in a steam steriliser.

Packaging & Labelling: One (1) forceps in a plastic bag.

Symbols Used: According to ISO 15223.

CE Mark: Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC, CE self-declaration, ISO 13845:2003 certified.

Classification: Class I - Medical Device Directive 93/42/EEC.

Safety & Product Standards: Must comply with the following standards: ISO 7153-1:1991, ISO 7151:1988, ISO 17664:2004, ISO 13402:1995.

88	Forceps, tissue, Allis, 4 x 5 teeth, 15 cm	Each	56	Instruments
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Product Description: Allis forceps for gripping soft tissue.

Material: Martensitic stainless steel (quenched magnetic steel) composition: From 0.16% to 0.25% carbon and from 12 to 14% chromium.

Features: Springy atraumatic style jaws; highly impact resistant; 4 x 5 teeth; precision adjustment of jaw teeth; hard ratchet (lockable).

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Length: Approx. 150 mm.

Supplied with: Manufacturers instruction for use.

Instructions for Use: Used to grip soft tissue. This item must be cleaned and disinfected after each use and sterilised in a steam steriliser.

Packaging & Labelling: One (1) forceps in a plastic bag.

Symbols Used: According to ISO 15223.

CE Mark: Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC, CE self-declaration, ISO 13845:2003 certified.

Classification: Class I - Medical Device Directive 93/42/EEC.

Safety & Product Standards: Must comply with the following standards: ISO 7153-1:1991, ISO 7151:1988, ISO 17664:2004, ISO 13402:1995.

89	Forceps, tissue, Babcock, 20 cm	Each	28	Instruments
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Product Description: Forceps Babcock for gripping soft and delicate tissues (lungs and intestines) and organs.

Material: Martensitic stainless steel (quenched magnetic steel) composition: From 0.16% to 0.25% carbon and from 12 to 14% chromium.

Features: Springy; high impact resistant; flexible arms; soft ratchet (lockable); pronounced but non-traumatic ridges of the grippers; ridged grippers with aperture (triangular).

Length: Approx. 200 mm.

Supplied with: Manufacturers instruction for use.

Instructions for Use: Used to grip soft and delicate tissues (lungs and intestines) and organs. This item must be cleaned and disinfected after each use and sterilised in a steam steriliser.

Packaging & Labelling: One (1) forceps in a plastic bag.

Symbols Used: According to ISO 15223.

CE Mark: Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC, CE self-declaration, ISO 13845:2003 certified.

Classification: Class I - Medical Device Directive 93/42/EEC.

Safety & Product Standards: Must comply with the following standards: ISO 7153-1:1991, ISO 7151:1988, ISO 17664:2004.

90	Forceps, tissue, Duval, 23 cm	Each	56	Instruments
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Product Description: Forceps Duval for gripping and holding bulky soft and delicate tissues (lung and intestines).

Material: Martensitic stainless steel (quenched magnetic steel); composition: 0.20% carbon; 13% chromium.

Features: 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: Approx. 230 mm.

Jaw Size: Approximately 27 mm.

Supplied with: Manufacturers instruction for use.

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Instructions for Use: Used to grip and hold bulky soft and delicate tissues (lung and intestines). This item must be cleaned and disinfected after each use and sterilised in a steam steriliser.

Packaging & Labelling: One (1) forceps in a plastic bag.

Symbols Used: According to ISO 15223.

CE Mark: Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC, CE self-declaration, ISO 13845:2003 certified.

Classification: Class I - Medical Device Directive 93/42/EEC.

Safety & Product Standards: Must comply with the following standards: ISO 7153-1:1991, ISO 7151:1988, ISO 17664:2004, ISO 13402:1995.

91	Forceps, tissue, standard, 145 mm, straight	Each	28	Instruments
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Product Description: 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.

Type: Dissecting forceps, spring-type; 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: Approx. 145 mm.

Instructions for Use: Used for gripping and dissecting tissue and coagulation of vessels. Used in surgery and nursing. Forceps with teeth are specifically for dissecting thick tissues. This item must be cleaned and disinfected after each use and sterilised in a steam steriliser.

Supplied With: Manufacturers instruction for use.

Packaging & 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 to ISO 15223 and EN 980.

CE Mark: Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC, CE self-declaration, ISO 13485:2003 certified.

Classification: Class I - Medical Device Directive 93/42/EEC.

Safety & Product Standards: Must comply with the following standards:

- ISO 13485:2003 Quality management systems - Requirements for regulatory purposes
- ISO 14971:2007 Medical Devices - Application of risk management to medical devices
- ISO 7153-1:1991/Amd1:1999 Surgical instruments - Metallic material – Part 1 Stainless Steel
- 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 17664:2004 Sterilization of medical devices - Information to be provided by the manufacturer for the processing of re-sterilizable medical devices

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92	Forceps, tissue, standard, 250 mm, straight	Each	28	Instruments
<p>Product Description: Dissecting forceps used in deep surgery for gripping and dissecting tissues, as well as coagulation of vessels. Forceps with teeth are designed for dissecting thick tissues.</p> <p>Type: Dissecting forceps, spring-type; straight with 1 x 2 teeth; flexible arms; good adjustment of the teeth; good jaw grips.</p> <p>Material: Martensitic steel (quenched magnetic steel); highly impact resistant.</p> <p>Length: Approx. 250 mm.</p> <p>Instructions for Use: Used for gripping and dissecting tissue and coagulation of vessels. Applicable in surgery and nursing. Forceps with teeth are specifically for dissecting thick tissues. This item must be cleaned and disinfected after each use and sterilised in a steam steriliser.</p> <p>Supplied With: Manufacturer's instruction for use.</p> <p>Packaging & Labelling: One (1) forceps in a plastic bag.</p> <ul style="list-style-type: none"> 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). <p>Symbols Used: According to ISO 15223 and EN 980.</p> <p>CE Mark: Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC, CE self-declaration, ISO 13485:2003 certified.</p> <p>Classification: Class I - Medical Device Directive 93/42/EEC.</p> <p>Safety & Product Standards: Must comply with the following standards:</p> <ul style="list-style-type: none"> ISO 13485:2003 Quality management systems - Requirements for regulatory purposes ISO 14971:2007 Medical Devices - Application of risk management to medical devices ISO 7153-1:1991/Amd1:1999 Surgical instruments - Metallic material – Part 1 Stainless Steel 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 17664:2004 Sterilization of medical devices - Information to be provided by the manufacturer for the processing of re-sterilizable medical devices 				
93	Bowl, stainless steel, 500 ml	Each	28	Instruments
<p>Product Description: Receptacle for liquids and other materials used before and during operations. A round container made of stainless steel with a smooth, non-glare surface.</p> <p>Material: Austenitic stainless steel (non-quenched, non-magnetic).</p> <p>Design Features:</p> <ul style="list-style-type: none"> Smooth walls without serrations. Thickness: Minimum 0.8 mm. Capacity: Approx. 500 to 600 ml. 				

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- Inner Diameter: Approx. 120 mm.
 - Height: Approx. 60 mm.
- Packaging & Labelling:**
- **Primary Packaging:** Unit of use: One (1) stainless steel bowl protected by adhesive plastic film.
 - **Labelling on Primary Packaging:**
 - Name and/or trademark of the manufacturer.
 - Manufacturer's product reference.
 - Type of product and main characteristics.
 - If the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging.
 - Lot number prefixed by the word LOT (or equivalent harmonised symbol) if applicable.
 - Information for particular storage conditions (temperature, pressure, light, humidity, etc.) as appropriate (or equivalent harmonised symbol).
 - Information for handling if applicable (or equivalent harmonised symbol).
 - **Over Packaging:** Packaging unit of X round bowls in a box.
 - **Labelling on Packaging Unit:** Labelling to be the same as primary packaging.
 - **Extra Information Required:** Number of units per box.
- Symbols Used:** According to ISO 15223.
- CE Mark:** Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC, CE self-declaration, ISO 13485:2003 certified.
- Classification:** 93/42/EEC Class I – Self-declaration / CE certification.
- Instructions for Use:** Basic equipment for nursing and surgical care. The size has been chosen as being the most commonly used.
- Note:** Do not use a stainless steel container to hold a chlorine solution as this may damage the stainless steel; use a plastic container. This item must be cleaned and disinfected after each use. It can be sterilized in a steam sterilizer when necessary.
- Safety & Product Standards:** Must comply with the following standards:
- ISO 7153-1:1991 Surgical instruments - Metallic materials.

94	Retractor, abdominal, Collin, three blades	Each	28	Instruments
<p>Product Description: Abdominal retractor with a locking mechanism (self-holding). Features three (3) blades, with the two side blades being mobile and the middle blade removable. Used to retract the abdominal wall and viscera to provide good exposure of the operative field.</p> <p>Material: Martensitic steel (quenched magnetic steel).</p> <p>Composition: From 0.42% to 0.55% carbon; from 12% to 15% chromium; from 0.45% to 0.9% molybdenum.</p> <p>Dimensions:</p> <ul style="list-style-type: none">• Solid Lateral Blades: Approx. 38 x 60 mm.				

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- **Solid Center Blade:** Approx. 38 x 55 mm.
- **Maximum Wound Opening:** Approx. 100 mm.
- **Solid Center Blade (Alternate Size):** Approx. 45 x 80 mm.
- **Maximum Wound Opening (Alternate Size):** Approx. 180 mm.

Supplied With: Manufacturer's instruction for use.

Instructions for Use: Used to retract skin, fatty tissue, muscles, or viscera after the incision to expose the operative field. This item must be cleaned and disinfected after each use and sterilized in a steam sterilizer.

Packaging & Labelling:

- **Primary Packaging:** Unit of use: One (1) retractor in a plastic bag.
- **Labelling on Primary Packaging:**
 - Name and/or trademark of the manufacturer.
 - Manufacturer's product reference.
 - Type of product and main characteristics.
 - If the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging.
 - Lot number prefixed by the word LOT (or equivalent harmonised symbol) if applicable.
 - Information for particular storage conditions (temperature, pressure, light, humidity, etc.) as appropriate (or equivalent harmonised symbol).
 - Information for handling if applicable (or equivalent harmonised symbol).

Symbols Used: According to ISO 15223.

CE Mark: Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC, CE self-declaration, ISO 13845:2003 certified.

Classification: Class I (MDD 93/42/EEC).

Safety & Product Standards: Must comply with the following standards:

- ISO 7153-1:1991 Surgical instruments - Metallic materials - Part 1: Stainless steel.
- ISO 7151:1988 Surgical instruments - Non-cutting articulated instruments - General requirements and test methods.
- ISO 17664:2004 Sterilization of medical devices - Information to be provided by the manufacturer for the processing of re-sterilizable medical devices.

95	Retractor, abdominal, Balfour, three blades	Each	28	Instruments
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Product Description: Used to retract the abdominal wall and viscera to provide good exposure during a laparotomy. The suprapubic abdominal retractor features a locking mechanism and a compass (self-holding). The compass acts as a support with hinged arms.

Material: Martensitic steel (quenched magnetic steel).

Composition: From 0.42% to 0.55% carbon; from 12% to 15% chromium; from 0.45% to 0.9% molybdenum.

Dimensions:

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- **Fenestrated End Blades:** Approx. 35 x 70 mm.
- **Solid Center Blade:** Approx. 45 x 80 mm.
- **Maximum Wound Opening:** Approx. 180 mm.

Supplied With: Manufacturer's instruction for use.

Instructions for Use: Used to retract skin, fatty tissue, muscles, or viscera after the incision to expose the operative field. This item must be cleaned and disinfected after each use and sterilized in a steam sterilizer.

Packaging & Labelling:

- **Primary Packaging:** Unit of use: One (1) retractor in a plastic bag.
- **Labelling on Primary Packaging:**
 - Name and/or trademark of the manufacturer.
 - Manufacturer's product reference.
 - Type of product and main characteristics.
 - If the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging.
 - Lot number prefixed by the word LOT (or equivalent harmonised symbol) if applicable.
 - Information for particular storage conditions (temperature, pressure, light, humidity, etc.) as appropriate (or equivalent harmonised symbol).
 - Information for handling if applicable (or equivalent harmonised symbol).

Symbols Used: According to ISO 15223.

CE Mark: Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC, CE self-declaration, ISO 13845:2003 certified.

Classification: Class I (MDD 93/42/EEC).

Safety & Product Standards: Must comply with the following standards:

- ISO 7153-1:1991 Surgical instruments - Metallic materials - Part 1: Stainless steel.
- ISO 7151:1988 Surgical instruments - Non-cutting articulated instruments - General requirements and test methods.
- ISO 17664:2004 Sterilization of medical devices - Information to be provided by the manufacturer for the processing of re-sterilizable medical devices.

96	Retractor, double-ended, Farabeuf, 15 cm, pair	Pair	28	Instruments
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Product Description: Used to retract skin, subcutaneous tissues, muscles, or viscera during surgery. The retractor features a double-ended handle with angled blades.

Material: Austenitic stainless steel (non-quenched, non-magnetic steel).

Composition: 18% to 20% chromium; 8% to 10% nickel.

Dimensions:

- **Blade Size:** One end 24 x 16 mm; the other end 28 x 16 mm.

<ul style="list-style-type: none">● Length: Approx. 150 mm.● Supplied in: Pairs. <p>Supplied With: Manufacturer's instruction for use.</p> <p>Instructions for Use: Used to retract skin, fatty tissue, muscles, or viscera during superficial surgery. This item must be cleaned and disinfected after each use and sterilized in a steam sterilizer.</p> <p>Packaging & Labelling:</p> <ul style="list-style-type: none">● Unit Presentation: Individually in protective packaging.● Packaging Information:<ul style="list-style-type: none">○ Designation of the instrument.○ Name and address of the supplier (manufacturer). <p>Symbols Used: According to ISO 15223.</p> <p>CE Mark: Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC, CE self-declaration, ISO 13845:2003 certified.</p> <p>Classification: Class I (MDD 93/42/EEC).</p> <p>Safety & Product Standards: Must comply with the following standards:</p> <ul style="list-style-type: none">● ISO 7153-1:1991 Surgical instruments - Metallic materials - Part 1: Stainless steel.● ISO 13402:1995 Surgical and dental hand instruments - Determination of resistance against autoclaving, corrosion, and thermal exposure.● ISO 17664:2004 Sterilization of medical devices - Information to be provided by the manufacturer for the processing of re-sterilizable medical devices.				
97	Scalpel handle no. 4, blade holder, 13 cm	Each	28	Instruments
<p>Product Description: A handle into which small surgical blades are inserted, used for surgical incisions (compatible with blades .20, .21, .22, and .23). Intended for use by surgeons only.</p> <p>Material: Austenitic steel (non-quenched, non-magnetic steel).</p> <p>Composition: 17% to 19% chromium; 8% to 10% nickel.</p> <p>Dimensions:</p> <ul style="list-style-type: none">● Length: Approx. 135 mm. <p>Supplied With: Manufacturer's instruction for use.</p> <p>Accessories/Spare Parts/Consumables:</p> <ul style="list-style-type: none">● The handle is compatible with the following sized surgical blades (Note: Blades are sold separately):<ul style="list-style-type: none">○ Scalpel blade sterile disposable no. 20.○ Scalpel blade sterile disposable no. 21.○ Scalpel blade sterile disposable no. 22.○ Scalpel blade sterile disposable no. 23.				

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Instructions for Use: To hold a blade for surgical incisions. This handle is to be used with disposable blades. It must be cleaned and disinfected after each use and sterilized in a steam sterilizer. Intended for use by surgeons only.

Packaging & Labelling:

- **Primary Packaging:** Unit of use: One (1) scalpel in a plastic bag.
- **Labelling Information:** Product name, size, reference number, expiry date, lot number, sterilization method, manufacturer's name and address, CE mark, and reference number of the notifying body. Must be multilingual (English, French, and Spanish, with others when available).
- **Protective Packaging:** Box of 10 units; cardboard labelling is the same as unit presentation with the total quantity.

Symbols Used: According to ISO 15223.

CE Mark: Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC, CE self-declaration, ISO 13845:2003 certified.

Classification: Class I (MDD 93/42/EEC).

Safety & Product Standards: Must comply with the following standards:

- ISO 7153-1:1991 Surgical instruments - Metallic materials - Part 1: Stainless steel.
- ISO 13402:1995 Surgical and dental hand instruments - Determination of resistance against autoclaving, corrosion, and thermal exposure.
- EN 27740/ISO 7740: Scalpels with detachable blades fitting dimensions.
- ISO 17664:2004 Sterilization of medical devices - Information to be provided by the manufacturer for the processing of re-sterilizable medical devices.

98	Scissors, Metzenbaum/Nelson, 18 cm, curved, blunt/blunt	Each	28	Instruments
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Product Description: Surgical dissecting scissors Metzenbaum/Nelson, used in the fine dissection of tissues.

Material: Martensitic stainless steel (quenched magnetic steel).

Composition: 0.40% carbon; 14% chromium.

Design: Thin curved blades with blunt ends.

Length: Approx. 180 mm.

Supplied With: Manufacturer's instruction for use.

Instructions for Use: These surgical dissecting scissors are designed for the fine dissection of tissues. They must be cleaned and disinfected after each use and sterilized in a steam sterilizer.

Packaging & Labelling:

- **Unit Presentation:** Individually packaged in protective packaging.
- **Labeling Information:**
 - Designation of the instrument.
 - Name and address of the supplier (manufacturer).

Symbols Used: According to ISO 15223.

<p>CE Mark: Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC, CE self-declaration, ISO 13845:2003 certified.</p> <p>Classification: Class I (MDD 93/42/EEC).</p> <p>Safety & Product Standards: Must comply with the following standards:</p> <ul style="list-style-type: none">• ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.• ISO 7153-1:1991 Surgical instruments - Metallic materials - Part 1: Stainless steel.• ISO 13402:1995 Surgical and dental hand instruments - Determination of resistance against autoclaving, corrosion, and thermal exposure.• ISO 7741:1986 Instruments for surgery - Scissors and shears - General requirements and test methods.• ISO 17664:2004 Sterilization of medical devices - Information to be provided by the manufacturer for the processing of re-sterilizable medical devices.				
99	Scissors, Metzenbaum/Nelson, 23 cm, curved, blunt/blunt	Each	28	Instruments
<p>Product Description: Surgical dissecting scissors Metzenbaum/Nelson, used in the fine dissection of tissues.</p> <p>Material: Martensitic stainless steel (quenched magnetic steel).</p> <p>Composition: 0.40% carbon; 14% chromium.</p> <p>Design: Thin curved blades with blunt ends.</p> <p>Length: Approx. 230 mm.</p> <p>Supplied With: Manufacturer's instruction for use.</p> <p>Instructions for Use: These surgical dissecting scissors are designed for the fine dissection of tissues. They must be cleaned and disinfected after each use and sterilized in a steam sterilizer.</p> <p>Packaging & Labelling:</p> <ul style="list-style-type: none">• Unit Presentation: Individually packaged in protective packaging.• Labeling Information:<ul style="list-style-type: none">○ Designation of the instrument.○ Name and address of the supplier (manufacturer). <p>Symbols Used: According to ISO 15223.</p> <p>CE Mark: Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC, CE self-declaration, ISO 13845:2003 certified.</p> <p>Classification: Class I (MDD 93/42/EEC).</p> <p>Safety & Product Standards: Must comply with the following standards:</p> <ul style="list-style-type: none">• ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.• ISO 7153-1:1991 Surgical instruments - Metallic materials - Part 1: Stainless steel.• ISO 13402:1995 Surgical and dental hand instruments - Determination of resistance against autoclaving, corrosion, and thermal exposure.				

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<ul style="list-style-type: none">ISO 7741:1986 Instruments for surgery - Scissors and shears - General requirements and test methods.ISO 17664:2004 Sterilization of medical devices - Information to be provided by the manufacturer for the processing of re-sterilizable medical devices.				
100	Scissors, Mayo, 23 cm, curved, blunt/blunt	Each	28	Instruments
<p>Product Description: Surgical dissecting scissors Mayo, used for non-delicate dissections and to cut sutures and dressings.</p> <p>Material: Martensitic stainless steel (quenched magnetic steel).</p> <p>Composition: 0.40% carbon; 14% chromium.</p> <p>Design: Instrument that cuts by shearing with thin curved blades and blunt ends.</p> <p>Length: Approx. 230 mm.</p> <p>Supplied With: Manufacturer's instruction for use.</p> <p>Instructions for Use: These surgical dissecting scissors are intended for non-delicate dissections and for cutting sutures and dressings. They must be cleaned and disinfected after each use and sterilized in a steam sterilizer.</p> <p>Packaging & Labelling:</p> <ul style="list-style-type: none">Unit Presentation: Individually packaged in protective packaging.Labeling Information:<ul style="list-style-type: none">Designation of the instrument.Name and address of the supplier (manufacturer). <p>Symbols Used: According to ISO 15223.</p> <p>CE Mark: Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC, CE self-declaration, ISO 13845:2003 certified.</p> <p>Classification: Class I (MDD 93/42/EEC).</p> <p>Safety & Product Standards: Must comply with the following standards:</p> <ul style="list-style-type: none">ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.ISO 7153-1:1991 Surgical instruments - Metallic materials - Part 1: Stainless steel.ISO 13402:1995 Surgical and dental hand instruments - Determination of resistance against autoclaving, corrosion, and thermal exposure.ISO 7741:1986 Instruments for surgery - Scissors and shears - General requirements and test methods.ISO 17664:2004 Sterilization of medical devices - Information to be provided by the manufacturer for the processing of re-sterilizable medical devices.				
101	Spatula, Ribbon retractor, malleable, 27 × 250 mm	Each	28	Instruments
<p>Product Description: Used to retract tissues, muscles, or viscera in abdominal incisions.</p> <p>Materials: Austenitic steel (non-quenched non-magnetic steel).</p> <p>Specifications:</p> <ul style="list-style-type: none">Type: Depressor spatula, rectangular with rounded ends.				

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<ul style="list-style-type: none">• Dimensions: Approx. 27 x 250 mm.• Reusability: Reusable. <p>Instructions for Use: This instrument is used to retract tissues, muscles, or viscera during abdominal incisions. It must be cleaned and disinfected after each use and sterilized in a steam sterilizer.</p> <p>Supplied With: Manufacturer's instruction for use.</p> <p>Packaging & Labelling:</p> <ul style="list-style-type: none">• Unit Presentation: One (1) spatula in a plastic bag.• Labeling Information on Primary Packaging:<ul style="list-style-type: none">○ Name and/or trademark and address of the manufacturer.○ Manufacturer's product reference.○ Lot number prefixed by the word LOT (or equivalent harmonized symbol if applicable).○ Symbols used according to ISO 15223 and EN 980. <p>CE Mark: Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC, CE self-declaration, ISO 13485:2003 certified.</p> <p>Classification: Class I - Medical Device Directive 93/42/EEC.</p> <p>Safety & Product Standards: Must comply with the following standards:</p> <ul style="list-style-type: none">• ISO 13485: 2003 Quality management systems - Requirements for regulatory purposes.• ISO 14971:2007 Medical Devices - Application of risk management to medical devices.• ISO 7153-1:1991/Amd1:1999 Surgical instruments - Metallic material - Part 1: Stainless Steel.• ISO 13402:1995 Surgical and dental hand instruments - Determination of resistance against autoclaving, corrosion, and thermal exposure.• ISO 17664:2004 Sterilization of medical devices - Information to be provided by the manufacturer for the processing of re-sterilizable medical devices.				
102	Tube, suction, Yankauer, 28 cm	Each	28	Instruments
<p>Product Description: Suction tube with removable tip and tubing connector used for aspirating fluids/secretions from the operative area.</p> <p>Materials: Austenitic steel (non-quenched non-magnetic steel).</p> <ul style="list-style-type: none">• Composition: 16 to 18% chromium; 10 to 14% nickel; 2 to 3% molybdenum. <p>Specifications:</p> <ul style="list-style-type: none">• Type: Curved suction tube.• Length: Approx. 280 mm.• Diameter: Approx. 6 mm or 8 mm. <p>Instructions for Use: This instrument is used for aspirating fluids/secretions from the operative area.</p> <p>Safety Process: This item must be cleaned, disinfected after each use, and sterilized in a steam sterilizer.</p> <p>Supplied With: Manufacturer's instruction for use.</p>				

<p>Packaging & Labelling:</p> <ul style="list-style-type: none">• Primary Packaging: One (1) suction tube in a plastic bag.• Secondary Packaging: Protected unit; ten (10) suction tubes in a box.• Labeling Symbols: Symbols used according to ISO 15223. <p>CE Mark: Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC, CE self-declaration, ISO 13845:2003 certified.</p> <p>Classification: 93/42/EEC Class I – Self-declaration / CE certified.</p>				
103	Cranioclast, Braun, 420 mm	Each	28	Instruments
<p>Product Description: Cranioclast Braun for gripping and decreasing the fetal skull in case of death in utero, allowing for vaginal extraction. Pressure force instrument with adjustable screw clamp.</p> <p>Materials: Martensitic (quenched magnetic steel).</p> <p>Specifications:</p> <ul style="list-style-type: none">• Length: 42 cm. <p>Instructions for Use: This instrument is used to crush the fetal skull, permitting vaginal extraction of fetal parts following death in utero (embryotomy).</p> <p>Safety Process: This item must be cleaned, disinfected after each use, and sterilized in a steam sterilizer.</p> <p>Supplied With: Manufacturer's instruction for use.</p> <p>Packaging & Labelling:</p> <ul style="list-style-type: none">• Primary Packaging: Unit of use; one (1) cranioclast in a plastic bag.• Labeling on the Primary Packaging:<ul style="list-style-type: none">○ Name and/or trademark and address of the manufacturer.○ Manufacturer's product reference.○ Type of product and main characteristics.○ Lot number prefixed by the word LOT (or equivalent harmonized symbol if applicable).○ Information for particular storage conditions (temperature, pressure, light, humidity, etc. as appropriate, or equivalent harmonized symbol).○ Symbols used according to ISO 15223 and EN 980. <p>CE Mark: Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC, CE self-declaration, ISO 13485:2003 certified.</p> <p>Classification: Class I - Medical Device Directive 93/42/EEC.</p> <p>Safety & Product Standards:</p> <ul style="list-style-type: none">• ISO 13485:2003 Quality management systems – Requirements for regulatory purposes.• ISO 14971:2007 Medical Devices - Application of risk management to medical devices.• ISO 7153-1:1991/Amd1:1999 Surgical instruments - Metallic material – Part 1 Stainless Steel.				

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- 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 17664:2004 Sterilization of medical devices – Information to be provided by the manufacturer for the processing of re-sterilizable medical devices.

Environmental Requirements: Not to use PVC polymer.

104	Perforator, Smellie, 25 cm	Each	28	Instruments
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Product Description: Perforator Smellie for piercing the fetal skull and reducing its diameter in case of death in utero, allowing for vaginal extraction.

Materials: Martensitic steel (quenched magnetic steel).

- **Composition:** 0.40% carbon; 14% chromium.
- **Cutting Mechanism:** Cuts by perforating shears.

Specifications:

- **Length:** approx. 250 mm.

Supplied With: Manufacturer's instruction for use.

Instructions for Use: This instrument is used to pierce the fetal skull and reduce its diameter in case of death in utero to permit vaginal extraction.

Safety Process: This item must be cleaned, disinfected after each use, and sterilized in a steam sterilizer.

Packaging & Labelling:

- **Primary Packaging:** One (1) perforator in a plastic bag.
- **Symbols Used:** According to ISO 15223.

CE Mark: Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC, CE self-declaration, ISO 13485:2003 certified.

Classification: Class I - Medical Device Directive 93/42/EEC.

Safety & Product Standards: Must comply with the following standards: ISO 7153-1:1991. ISO 17664:2004. ISO 13402:1995. ISO 7741:1986. BS 5194-4:1985.

105	Hook, decapitation, Braun, 31 cm	Each	28	Instruments
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Product description: Obstetrical hook for the vaginal extraction of a dead foetus in utero (embryotomy) meant for use by experienced doctors.

Material: Martensitic stainless steel (quenched magnetic steel) composition: 0.20% carbon; 13% chromium.

Length: approx. 310 mm

Supplied with: Manufacturers instruction for use.

Instructions for use: Used to extract the foetus through the vagina in case of death in uterus. This item must be cleaned, disinfected after each use, and sterilised in a steam steriliser.

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<p>Packaging & Labelling: One (1) Hook in a plastic bag.</p> <p>Symbols used according to ISO 15223</p> <p>Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC, CE self-declaration, ISO 13845:2003 certified.</p> <p>Classification: Class I - Medical Device Directive 93/42/EEC</p> <p>Safety & product Standards: Must comply with the following standards: ISO 7153-1:1991, ISO 17664:2004, ISO 13402:1995, ISO 7741:1986, BS 5194-4:1985.</p>				
106	Bowl, stainless steel, 180 ml	Each	28	Instruments
<p>Product description: Receptacle for liquids and other materials used before and during operations. Round container made of stainless steel with a smooth, non-glare surface.</p> <p>Material: Austenitic stainless steel (non-quenched non-magnetic) composition: 18 to 20% chromium and 8 to 10% nickel.</p> <p>Thickness: min. 0.8 mm.</p> <p>Capacity: 150 to 180 ml.</p> <p>Inner diameter: approx. 80 mm.</p> <p>Height: approx. 40 mm.</p> <p>Packaging and labelling:</p> <p>Primary packaging: Unit of use: One (1) stainless steel bowl protected by adhesive plastic film.</p> <p>Labelling on the primary packaging: Name and/or trademark of the manufacturer, manufacturers product reference, type of product and main characteristics. If the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging. Lot number prefixed by the word LOT (or equivalent harmonised symbol) if applicable. Information for particular storage conditions (temperature, pressure, light, humidity, etc.) as appropriate (or equivalent harmonised symbol). Information for handling if applicable (or equivalent harmonised symbol).</p> <p>Over packaging: Packaging unit: X Round bowls in a box.</p> <p>Labelling on the packaging unit: Labelling to be the same as primary packaging.</p> <p>Extra information required: Number of units per box.</p> <p>Symbols used according to ISO 15223</p> <p>CE Mark</p> <p>Instructions for use: Basic equipment for nursing and surgical care. The size has been chosen as being the most commonly used.</p> <p>Note: Do not use a stainless steel container to hold a chlorine solution as this may damage the stainless steel; use a plastic container. This item must be cleaned, disinfected after each use, and can be sterilized in a steam sterilizer when necessary.</p> <p>Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC, CE self-declaration, ISO 13485:2003 certified.</p> <p>Classification: 93/42/EEC Class I – Self declaration / CE cert.</p> <p>Safety & product Standards: Must comply with the following standards: ISO 7153-1:1991.</p>				

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107	Chlorhexidine digluconate 5% solution, 1-litre bottle	Bottle	2,196	IPC
Chlorhexidine digluconate 7.1% gel tube 20g. Labelling: products should be clearly labelled for cord care. Preferably a pictorial representation on how the gel will be applied is included on the label.				
108	Safety box, disposal of used syringes and needles, 5 litres	Each	2,348	IPC
<p>Product description: Syringe disposal container for safe handling and disposing of 100 (Auto Disable) syringes.</p> <p>Material: Recycled cardboard with a strong plastic film (waterproof and puncture-proof).</p> <p>Thickness of walls: 1.1 - 4.4 mm.</p> <p>Container capacity: 5 L accommodating approximately 100 syringes.</p> <p>Dimensions: approx. 284 x 162 x 129 mm when set up.</p> <p>Features: Notching system for hermetic sealing (inferior and superior parts), diameter of syringe insert hole: 30-38 mm. Boxes should be equipped with a carrying handle and have directions for use and destruction printed on the box. Distributed and stored in collapsible form.</p> <p>Single use: To be destroyed with its contents by incineration.</p> <p>Instructions for use: Puncture-resistant containers for collecting and disposing of used disposable and auto-disable syringes, needles, and other injection materials must be provided and used in all immunization activities. These containers reduce the risk posed by contaminated needles and syringes to health staff and the general public.</p> <p>Supplied with: 25 boxes in one carton, flat-packed for assembly by the end-user + manufacturers instruction for use.</p> <p>Packaging and labelling:</p> <p>Primary packaging: Unit presentation: 1 (one) safety box for used syringes/needles 5 L set/25.</p> <p>Symbols used according to ISO 15223</p> <p>CE Mark</p> <p>Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC, CE self-declaration, ISO 13485:2003 certified.</p> <p>Classification: 93/42/EEC Class I – Self declaration / CE cert.</p> <p>Safety & product Standards: Must comply with the following standards: WHO Performance Specification E10/IC.1, ASTM F2132 - 01(2008)e1 Standard Specification for Puncture Resistance of Materials Used in Containers for Discarded Medical Needles and Other Sharps.</p> <p>Environmental requirements: It is recommended to use other polymers, not PVC.</p>				
109	Brush, hand, scrubbing, plastic	Each	432	IPC
<p>Product description: To be used for scrubbing hands prior to surgical intervention. Brush with nylon bristles on a plastic block.</p> <p>Soft bristles: Minimum 5 rows.</p> <p>Material: - Head: Polypropylene; - Bristles: Nylon.</p> <p>Dimensions: Length: head approx. 8 - 10 cm, Width: approx. 3 - 5 cm, Height: approx. 1 cm.</p> <p>Reusable: Non-sterile.</p>				

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Instructions for use: Plastic brush for scrubbing hands in general and specifically prior to surgery. This brush must be of a plastic type that can be autoclaved after cleaning and disinfection. Do not use a brush with a wooden head, as cracks in the wood may harbor contamination. The size has been chosen as being the most commonly used.

Safety process: This item is used as a "clean" or "sterile" item. The item must be cleaned, disinfected, and sterilized in a steam sterilizer as often as necessary.

Protection of users: Washing hands before and after each medical act is extremely important to limit the risk of cross-contamination. Wash hands as often as necessary. Prior to any medical act: Use water and soap for approximately 3 minutes. Prior to surgical purposes: Use distilled water and soap or disinfectant for approximately 8 minutes.

Supplied with: Manufacturers instruction for use.

Packaging and labelling:

Primary packaging: One (1) scrubbing brush in a plastic bag with manufacturer's instruction for use in English. Alternatively, the instruction for use can be indicated on a separate insert.

Secondary packaging: Protected unit; ten (10) scrubbing brushes in a box with manufacturer's instruction for use (when applicable).

Labelling on the primary packaging: Name and/or trademark of the manufacturer.

Symbols used according to ISO 15223 and EN 980.

CE mark.

Secondary packaging: Ten (10) scrubbing brushes in a box with manufacturer's instruction for use (when applicable).

Labelling on the secondary packaging: Name and/or trademark and address of the manufacturer, manufacturer's product reference, type of product and main characteristics, number of units per secondary packaging, information for particular storage conditions (temperature, pressure, light, humidity, etc.) as appropriate (or equivalent harmonised symbol), information for handling if applicable (or equivalent harmonised symbol).

Regulation & conformity requirements: CE mark conforming to Council Directive 93/42/EEC on Medical Devices, CE self-declaration, ISO 13485:2003 certificate.

Classification: Class I – Medical Device Directive (MDD 93/42/EEC).

Safety & product Standards: Must comply with the following standards: ISO 13485:2003 Medical devices -- Quality management systems -- Requirements for regulatory purposes, ISO 14971:2007 Medical Devices - Application of risk management to medical devices.

Environmental requirements: Not to use PVC polymer.

110	Glasses, safety, regular size, disposable	Each	208	IPC
<p>Product description: Security glasses to protect against blood and exposure to other human fluids during surgery, midwifery, and other medical procedures. Wraparound protective eyewear with a wide field view that fits over prescription eyewear. Lightweight and comfortable, easy to combine with the wearing of protective masks (surgical/respiratory masks) and over eyeglasses.</p> <p>Materials: Clear polycarbonate, latex-free, 99.9% UV protection.</p> <p>Features: Distortion-free, anti-fog, abrasion resistant, adapted to the shape of the face, integral side-shields, contoured nose bridge, flat side arms offering good sideways protection, and temple length preferably adjustable.</p>				

Weight: Approx. 40-60 g.

Standard size: Disposable.

Instructions for use: Security glasses to protect against blood and exposure to other human fluids during surgery, midwifery, and other medical procedures. Disposable glasses: to be destroyed if they are soiled or damaged; otherwise, they could be reused after cleaning with water and soap. Never use solvent.

Supplied with: Manufacturers instruction for use (in English and/or Arabic).

Packaging and labelling:

- **Primary packaging:** Unit of use: one (1) pair of protective glasses in a sealed plastic bag with instructions for use, product name, reference number, lot number, manufacturer's name and address, CE mark, the words "for single use" (or equivalent harmonised symbol), the words "destroy after use" (if space allows) or equivalent harmonised symbol, information for particular storage conditions (temperature, pressure, light, humidity, etc.) as appropriate (or equivalent harmonised symbol) if applicable.
- **Symbols used according to ISO 15223 and EN 980.**
- **Secondary packaging:** Protected unit.
- **Labelling on the secondary packaging:** Labelling to be the same as primary packaging.
- **Extra information required:** Number of units per secondary packaging.

Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC and Personal Protective Equipment (PPE) Directive 89/686/EEC, CE self-declaration, ISO 13485:2003 certified.

Classification: Class I – Medical Device Directive 93/42/EEC.

Safety & product Standards: Must comply with the following standards: ISO 13485:2003 Medical devices - Quality management systems -- Requirements for regulatory purposes, ISO 14971:2007 Medical Devices - Application of risk management to medical devices, EN 166:2001 Personal eye protection - Specification (optic class 1), EN 167:2001 Personal eye protection - Optical test methods, EN 170:202: Personal eye protection - Ultraviolet filters - Transmittance requirements and recommended use.

Environmental requirements: Not to use PVC.

111	Apron, protection, plastic, reusable	Each	152	IPC
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Product description: Protective apron to be worn by surgeon or midwife for protection. Straight apron with bib back fastening and neckband should be strong and not detachable. Moisture-proof and resistant to blood, water, chemicals, and stains.

Material: Opaque or translucent high-quality plastic material, withstanding washing, boiling, steam sterilization, and resistant to 0.5% chlorine.

Size: Adult size. Length: 120 cm (from top of the bib to lower edge of the apron). Width: 80 cm. Thickness: 0.15 - 0.30 mm.

Sterility: Non-sterile and reusable.

Instructions for use: Apron to be used in healthcare facilities by personnel performing medical, obstetrical, or surgical procedures with a high risk of contamination by body fluids projection. The size has been chosen as the most commonly used. After use, the apron must be washed, disinfected with chlorine solution (0.05% concentration), and dried. If the apron is damaged (perforation, etc.), it must be

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<p>disposed of in a waste container, collected, and destroyed. Please refer to WHO publication on Safe Management of Waste for Health Care.</p> <p>Supplied with: Manufacturers instruction for use.</p> <p>Packaging and labelling: Individually packaged in a transparent plastic bag. Product name, size, reference number, manufacturer's name and address, CE mark, the words “Non-sterile reusable” (or equivalent harmonised symbol), information for particular storage conditions (temperature, pressure, light, humidity, etc.) as appropriate (or equivalent harmonised symbol) if applicable. Symbols used according to ISO 15223.</p> <p>Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC, CE self-declaration, ISO 13845:2003 certified.</p> <p>Classification: Class I – Medical Device Directive 93/42/EEC.</p> <p>Safety & product Standards: Must comply with the following standards: ISO 22610:2006 Surgical drapes, gowns, and clean air suits used as medical devices for patients, clinical staff, and equipment - Test method to determine the resistance to wet bacterial penetration, ISO 22612:2005 Clothing for protection against infectious agents - Test method for resistance to dry microbial penetration.</p> <p>Environmental requirements: Not to use PVC.</p>				
112	Draw sheet, plastic, 90 × 180 cm, reusable	Each	152	IPC
<p>Product description: Rectangular plastic sheet used to protect equipment from soiling.</p> <p>Material: Opaque or translucent plastic (PVC).</p> <p>Dimensions: Width: 90-110 cm; Length: 150-180 cm; Thickness: 10-20 microns.</p> <p>Washing: Normal, withstands boiling and steam sterilization, resists 0.5% chlorine.</p> <p>Sterility: Reusable and non-sterile.</p> <p>Instructions for use: The draw sheet is used to protect examination, delivery, and operating tables and/or bed mattresses from soiling. The draw sheet must be washed, disinfected with chlorine solution (0.05% concentration), and dried after use. If the draw sheet is damaged (perforation, etc.), it must be disposed of in a waste container, collected, and destroyed. Please refer to WHO publication on Safe Management of Waste for Health Care.</p> <p>Supplied with: Manufacturers instruction for use.</p> <p>Packaging and labelling:</p> <ul style="list-style-type: none">Primary packaging: Unit of use. One (1) plastic drawsheet in a plastic bag.Labelling: Product name, size, reference number, manufacturer's name and address, CE mark or similar, information for particular storage conditions (temperature, pressure, light, humidity, etc.) as appropriate (or equivalent harmonised symbol). <p>Regulation & conformity requirements: CE mark conforming to Medical Device Directive 93/42/EEC, CE self-declaration, ISO 13485:2003 certified.</p> <p>Classification: Class I – Medical Device Directive 93/42/EEC.</p>				
113	Bag, biohazard, yellow, 50 litres	Each	8,000	IPC

Annex 6 – Technical Specifications**ITB No. UNFPA/PAL/ITB/2024/012****Product description:** Yellow plastic bag for biohazardous infectious healthcare waste.**Material:** High molecular weight high density (HMHD) Polythene or Polypropylene (PP).**Colour:** Yellow.**Pattern:** Imprinted in black with English language text "Biohazard" and the black tri-sickle logo (U+2623) on both sides of the bag. An empty field is provided for an end-user to add their name and address.**Size:** Approx. 600 × 800 mm.**Capacity:** Approx. 50 L.**Thickness:** Minimum 0.050 mm.**Features:**

- With metal closure strip (one per bag).
- Puncture, tear, and leak resistant.
- Leak-proof bottom seal for added safety.
- Bag can be autoclaved prior to disposal at temperatures between +121°C and +135°C.
- Bags have a temperature indicator patch printed with chemically active ink. During autoclaving, the color changes, providing proof that the bag has been exposed to high temperatures for sterilization.

Supplied with: N/A.**Accessories / Spare Parts / Consumables:** Available but not supplied: N/A.**Intended use:** Instructions and warnings for use are printed onto the bag. The bag is not to be used if the product or packaging has been visually compromised. The bag must not be completely closed when autoclaving. It is printed with a sterilization patch that changes color when subject to steam sterilization.**Packaging and Labelling:** One (1) roll or box of one hundred (100) individual bags.

- Device identity and intended purpose.
- Manufacturer's product code or reference number.
- Manufacturer identification.
- Address of the manufacturing site.
- Instructions on how the device should be used, maintained, and stored.
- Lot/Batch and MFD.
- Any residual device risks, warnings, limitations, or contraindications.
- Symbols used according to ISO 15223.
- CE mark.

Regulation and Conformity Requirements:

- CE mark (conforming to Medical Device Directive MDD 93/42/EEC and MDR 2017/745) or FDA 510k approved or equivalent.
- Declaration of Conformity according to ISO 17050.
- ISO 13485 or ISO 9001 certified.

Classification: Class I medical device (MDD 93/42/EEC, MDR 2017/745).

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- ASTM D1922 - Tear resistance.
- It must meet or exceed the 165 g puncture inspection standard as described in ASTM D1709.

Environmental Requirements: ISO 14001: Environmental management systems.

114	Basket, instruments, for sterilization, wired, 400 × 200 × 90 mm	Each	28	IPC
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Product description: Stainless steel wired basket used as support for sterilizing surgical instruments.**Material:** Austenitic stainless steel (non-quenched, non-magnetic steel), AISI 316 L stainless steel.**Design:** Rectangular basket with rounded, not soldered corners; close mesh netting (4.5 x 4.5 mm); tilting handles.**Dimensions:** Approx. 400 x 200 x 90 mm.**Instructions for use:** This stainless steel wired basket is specifically designed to support the sterilization of surgical instruments.**Supplied with:** Manufacturer's instruction for use.**Packaging and Labelling:** One (1) sterilization basket in a protective plastic bag with manufacturer's instruction for use in English.

- **Labelling:**
 - Name and/or trademark and address of the manufacturer.
 - Manufacturer's product reference.
 - Symbols used according to ISO 15223 and EN 980.
 - CE mark.

Regulation and Conformity Requirements:

- CE mark conforming to Council Directive 93/42/EEC on Medical Devices.
- CE self-declaration.
- ISO 13485:2003 certificate.

Classification: Class I – Medical Device Directive (MDD 93/42/EEC).**Safety & Product Standards:** Must comply with the following standards:

- EN 10088-1: Stainless steels — Part 1: List of stainless steels.
- ISO 13485:2003: Medical devices — Quality management systems — Requirements for regulatory purposes.
- ISO 14971:2007: Medical Devices — Application of risk management to medical devices.

Environmental Requirements: Not to use PVC polymer.

115	Drape, surgical, woven, 100 × 150 cm	Each	168	IPC
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Product description: Square of woven fabric used to delimit the surgical intervention area in a patient and to maintain aseptic conditions in the operation area.**Material:** 100% cotton or 50% polyester - 50% cotton.**Fabric Specifications:** 50% polyester - 50% cotton fabric: Weight per m²: Approx. 175 g/m², Number of threads: Warp: 24; Weft: 22, Metric count: Warp: 28; Weft: 28, Cretonne cotton 100%: Weight per m²: Approx. 180 g, Number of threads/cm: Warp: 24; Weft: 24, Metric count: Warp: 28; Weft: 28

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Size: Approx. 100 x 150 cm.

Colour: Blue or green (not khaki-green). The colour quality must withstand repeated washings and sterilizations.

Washing: Normal; withstands boiling and steam sterilization; resistant to 0.5% chlorine. Non-sterile; reusable; washable.

Instructions for use: Used to delimit the surgical intervention area in a patient and to maintain aseptic conditions in the operation area. All new drapes must be washed prior to sterilization.

Supplied with: Manufacturer's instruction for use.

Packaging and Labelling:

- **Packaging:** Unit presentation: 1 drape non-sterile in a plastic bag with instructions for use.
- **Labelling:**
 - Name and/or trademark and address of the manufacturer.
 - Product name, size, and reference number.
 - Symbols used according to ISO 15223 and EN 980.
 - CE mark.

Regulation and Conformity Requirements:

- CE mark conforming to Medical Device Directive 93/42/EEC.
- CE self-declaration.
- ISO 13485:2003 certified.

Classification: Class I – Medical Device Directive 93/42/EEC.

Safety & Product Standards: Must comply with the following standards:

- ISO 13485:2003: Medical devices — Quality management systems — Requirements for regulatory purposes.
- ISO 14971:2007: Medical Devices — Application of risk management to medical devices.
- EN 13795:2011+A1:2013: Surgical drapes, gowns, and clean air suits used as medical devices for patients, clinical staff, and equipment. General requirements for manufacturers, processors, and products; test methods; performance requirements; and performance levels.
- ISO 17664:2004: Sterilization of medical devices — Information to be provided by the manufacturer for the processing of re-sterilizable medical devices.
- ISO 13934-1 and ISO 6330: Tensile strength loss after washing.

Environmental Requirements: Not to use PVC.

116	Test pregnancy, strip, temperature stable Test pregnancy strip temperature stable (P1)	Each	3,250	Laboratory
117	Test urinary protein, strip Screening test used for the detection of illnesses that show changes in urine particularly presence of proteins in urine.	Each	15,200	Laboratory
118	Bag (envelope), plastic, for drugs, 10 × 15 cm	Each	193,800	Other

Product description: Plastic tablet bag presented with three white write-on horizontal stripes clearly and cleanly printed on one side of the sachet, measuring approx. 100 x 15 mm for writing: Name of drug, Quantity, Dosage instructions, Date, Patient's Name.

Material: Virgin polyethylene.

Features:

- Self-sealing with minigrip type zip lock (also known as ziplock gripzeal or re-closable bags).

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- Moisture-resistant closure.
- Active length: Approx. 150 mm (length of the bag below the seal).
- Width: Approx. 100 mm.
- Thickness: 0.05 mm (50 microns).

Instructions for use: The sealable bag is used for the distribution of drugs to patients.

Supplied with: Manufacturer's instruction for use.

Packaging and Labelling: One plastic pack of 100 sachets.

Regulation & Conformity Requirements: QMS ISO 9001 certificate., CE mark conforming to Medical Device Directive 93/42/EEC., CE self-declaration., ISO 13485:2003 certified.

Classification: Class I – Self-declaration / CE certified per 93/42/EEC.

Safety & Product Standards: ISO 9001:2008.

Technical Standard: Product must comply with BS EN 71-3:2005 Safety of Toys - Part 3: Specifications for migration of certain elements.

Environmental Requirements: Use polymer materials other than PVC.

119	Sling, for use with infant scale	Each	380	Other
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Product description: Sling for use with spring-type infant scales to weigh babies for monitoring growth.

Material: Quality cotton fabric, strong and non-elastic.

Weight: Approx. 110 g (+/- 20 g).

Size: Square shape 80 x 80 cm prior to washing.

Features:

- Edges are double seam finished.
- Easy to iron.
- Corners can be knotted together to hold the baby securely when suspended from a birth weight indicator or scale.

Supplied with: Text and pictorial user instructions for usage and maintenance in English and/or Arabic; Bag for carrying and/or storage.

Instructions for use: Sling is used with spring-type infant scales to weigh babies for growth monitoring.

Packaging & Labelling: One (1) sling in a plastic bag + Information for user.

Symbols used according to ISO 15223: CE mark.

Regulation & Conformity Requirements: CE mark conforming to Council Directive 93/42/EEC on Medical Devices., CE self-declaration., ISO 13485:2003 certificate.

Classification: Class I – Self-declaration / CE certified per 93/42/EEC.

120	Kerosene storm lamp + extra socks	Each	76	Other
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Kerosene storm-lamp, feuhand hurricane, non-pressure for emergency lighting use.

- Complete with wick and clear globe (Suprax or similar heat resistant).
- Capacity: approx. 340ml.
- Supplies with 1 spare globe and 3 spare wicks.
- Certificate of conformity with ISO 9001.

Annex 6 – Technical Specifications**ITB No. UNFPA/PAL/ITB/2024/012**

121	Soap, hand, bar, 110 g, wrapped	Each	2,280	Other
<p>Bar of hand toilet soap.</p> <ul style="list-style-type: none"> - Composed of minimum Total Fatty Matter (TFM) 70%, water and volatiles maximum 24%, glycerine 1% and pH alkaline ingredients 5%. - Unperfumed or unscented. - Hypoallergenic. - Individually wrapped. - Weight: 110 to 125g. - Certificate of conformity with: BS 1914: 1990; or ASTM D501-03 (2009) 				
122	Indicator, TST control, spot, adhesive	Each	22,800	Other
<p>Product description: TST (Temperature Steam Time) control spot is an indicator to monitor the steam sterilization process, providing immediate feedback on the success of the sterilization cycle.</p> <p>Usage: For use in portable steam sterilizers operating at 121°C for 15 minutes.</p> <p>Indicator Features:</p> <ul style="list-style-type: none"> • Yellow reactive spot that changes to blue/purple after 15 minutes at 121°C in steam that is free of air. • Yellow spot remains unchanged if the sterilization cycle fails. • Self-adhesive spot, suitable for attachment to sterilizing drums or other steam sterilizing containers. <p>Diameter: Approx. 10 mm.</p> <p>Supplied with: One pack containing 300 TST control spots plus one record sheet; includes clear manufacturer's instructions for use in English, French, and Spanish.</p> <p>Instructions for use: TST control spots provide immediate indication of successful sterilization cycles.</p> <ul style="list-style-type: none"> • Use TST control spots systematically for each steam sterilization cycle. • Attach the TST control spot to the lid of the drum or steam sterilizing container. • Check the TST control spot when the sterilizing cycle is finished. • Record results of sterilization cycles (pass or fail) using the included record sheet. • If the TST control spot changes from yellow to blue, items in the drum can be used. If it does not change, items MUST NOT be used and must be re-sterilized with a new TST control spot. <p>Packaging & Labelling:</p> <ul style="list-style-type: none"> • Primary packaging: One (1) plastic pack containing 300 TST indicator spots. <ul style="list-style-type: none"> ○ Labelling includes: <ul style="list-style-type: none"> ▪ Name and/or trademark of the manufacturer. ▪ Manufacturer's product reference. ▪ Type of product and main characteristics. ▪ Lot number prefixed by "LOT" (or equivalent harmonised symbol, if applicable). ▪ Expiry date by year and month prefixed by "EXP" (or equivalent harmonised symbol, if applicable). ▪ The words "for single use" (or equivalent harmonised symbol). ▪ The words "destroy after use" (if space allows). ▪ Number of units per primary packaging (if applicable). ▪ Information for particular storage conditions (temperature, pressure, light, humidity, etc.) as appropriate (or equivalent harmonised symbol). ▪ Manufacturer's instructions for use (alternatively indicated on a separate insert). • Secondary packaging: Protected unit containing fifty (50) packs in a box. <ul style="list-style-type: none"> ○ Labelling to match primary packaging, including the number of units per secondary packaging. <p>Symbols used according to ISO 15223: CE mark.</p> <p>Regulation & Conformity Requirements: ISO 9001 certificate.</p> <p>Safety & Product Standards: Must comply with: ISO 9001:2008, ISO 11140-1:2005</p>				

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123	Gel, ultrasound, bottle, min. 250ml Product Description: Gel, ultrasound, bottle, min. 250ml	Tube	8,000	Other
124	LIDOCAINE HCl 2% STERILE GEL 11 GM	Tube	7,272	Other