

PHARMACEUTICALS AND MEDICAL DEVICES BUREAU OF INDIA (PMBI)

(Set up under the Department of Pharmaceuticals, Govt. of India)

B-500, B-Tower, 5th Floor, Nauroji Nagar, World Trade Center, New Delhi-110029

Amendment No. 3

Ref. Tender No: - PMBI/SURGICAL/RC-216/2024.

Dated: 04/09/2024

Subject: e-Tender No. PMBI/SURGICAL/RC-216/2024 dated 19/07/2024 for supply of Surgical/ Consumables & Medical Devices to Pharmaceuticals and Medical Devices Bureau of India (PMBI).

Pharmaceuticals and Medical Devices Bureau of India (PMBI) has invited bids from the interested parties for Supply of Surgical/ Consumables & Medical Devices for the year “2024-2026”, vide Notice Inviting e-Tender No.- PMBI/SURGICAL/RC-216/2024 dated 19/07/2024. Detailed tender document containing eligibility criteria, selection mechanism, other terms and conditions are available on the website of Central Public Procurement Portal; www.eprocure.gov.in and PMBI Website; www.janaushadhi.gov.in.

The following amendments in Tender Document are hereby authorized: -

Part- A:

S. No.	Tender Clause / Reference	Query / Suggestion	Clarification / Amendment
1.	Annexure -XII, Clause 18 (M): Detail Specification of Item	Bidder has requested to amend the detailed specification of item code 8133: Digital Blood Pressure Instrument (100% mercury free)	The amendment in detailed specification of item code 8133 is hereby authorized and may be read as: Digital Blood Pressure Instrument (100% mercury free): Fully Automated upper arm style with LCD Digital Display/ Digital monitor with WHO indicator and acrylic panel, Display shall show Numerical Data for reading. Displayed parameters: Unit should display systolic pressure, diastolic pressure, pulse rate Dimension: Design shall be handy and Portable and as per market standard. Display size shall be : 4.5-5.5 cm X 5 – 6 cm (± 1 cm) Measuring Method: Oscillometric technique. Measurement Range: Pressure- 0mmHg – 300 mmHg (0.00 kPa to 39.9 kPa), Pulse- 30 to 199 Beats/ Minute



			<p>Measurement Accuracy: Pressure- $\pm 3\text{mmHg}$ Pulse- $\pm 5\%$, Measurement time (s): ≤ 60, user selectable.</p> <p>Power supplies: AA/ AAA Alkaline Battery and Micro/ C-type/ Round Pin USB operated.</p> <p>Memory: 2 x 99 Memory (90-99 memory).</p> <p>Storage conditions: Temperature range when in use: from 5°C to 40°C. 15% to 90% RH.</p> <p>Storage and transport conditions: -20°C to 60°C. 10% to 95% RH.</p> <p>Equipment alarms preferred: Hose leak, inflation, or deflation error, Irregular Heartbeat Detection, Low Battery alarm, reading failure alarm.</p> <p>Accessories: High quality Arm Cuff (dimension 22 cm to 32 cm) with tube of suitable length, Protective case. USB Cable type-C (100cm), 4 AA/ AAA Alkaline battery set, User manual, Warranty Card.</p> <p>Shelf Life and warranty: Five Years and 2-years with replacement warranty (from the date of sale at Janaushadhi Kendra) Clinically validated algorithm International Standards: ISO 13485:2016 Certified/ FDA Certified/ CE certified.</p>
2.	Annexure -XII, Clause 18 (M): Detail Specification of Item	Bidder has requested to amend the detailed specification of item code 8136: Electric Nebulizer Machine.	<p>The amendment in detailed specification of item code 8136 is hereby authorized and may be read as:</p> <p>Electric Nebulizer Machine:</p> <p>Compressor Nebulizer Machine Motor: Piston Compressor Motor with 25mm Copper coated Aluminum binding.</p> <p>Particle Size: $< 0.5\text{ }\mu\text{m}$ (μm)</p> <p>Sound: 50-55 dB</p> <p>Standards and Safety Certificates: ISO 13485:2016 Certified, WHO-GMP Certified, FDA / CE; ISO 27427-2010.</p> <p>Warranty: 3 Years with replacement</p> <p>Weight (Ibs, kg)/ Design: $<1.5\text{ kg}$ and design shall be handy and Portable.</p> <p>Medication Cup: Shall be scaled for 2-6 ml medication</p> <p>Power Consumption: Product shall be power efficient</p> <p>Knob/Switch: Good quality indicator switch.</p>



			<p>Storage conditions: Temperature range when in use: from 5°C to 40°C. 15% to 90% RH.</p> <p>Storage and transport conditions: - 20°C to 60°C. 10% to 95% RH.</p> <p>Electric Cable: ISI certified 1.5 meter long, Plug shall be so designed to save from any shock while plugging in.</p> <p>Accessories: Compressor Nebulizer Machine, Adult mask, Child Mask, Mouthpiece, Medicine Cup, Filter (8pcs), Air Tube, Warranty Card, and Pouch.</p> <p>Nebulizer Mask with Tubing: shall be free from any kind of odour, made of clear, Non-toxic PVC, medium concentration, adjustable nose clip & non-autoclave Tube Length: 2-meter, Nebulization rate: 3cc / 10 mins.</p> <p>Packing: All the Accessories shall be supplied with good quality storage pouch (Made of clothing/durable material).</p>
3.	Annexure -XII, Clause 18 (M): Detailed specification of Item	Bidder has requested to amend the detailed specification of item code 9028: Medical Steam Vaporizer:	<p>The amendment in detailed specification of item code 9028 is hereby authorized and may be read as:</p> <p>Medical Steam Vaporizer:</p> <p>Model: Sleek style / Standard model</p> <p>Tank Capacity: 400-500ml</p> <p>Comfortable to use in Cough Sinus Nose Console, Steamer for Facial, Cold and Cough, Steam Machine for Face (vaporizer) Steam Vaporizer, Nose Steamer, Cough Steamer, Nozzle Inhaler & Nose vaporizer machine for cold and cough</p> <p>Body/ Material: 100% high grade plastic body with double wall protection to prevent shocks and heat injury. Sufficient space for easy cleaning.</p> <p>Electric Cable: ISI certified 1.5 meter long, Plug shall be so designed to save from any shock while plugging in.</p> <p>Water boiling time: 3-5 minutes</p> <p>Warranty: 2-year with replacement</p> <p>Accessory: Vaporizer with Nasal Aspirator and Steaming mask / Facial Attachment.</p> <p>Product shall be CE/ISO/FDA approved.</p>

4.	Annexure -XII, Clause 18 (M): Detailed specification of Item	Bidder has requested to amend the detailed specification of item code 9029: Digital Weighing Scale	No change <i>Tender condition prevails.</i>
5.	Annexure -XII, Clause 18 (M): Detailed specification of Item	Bidder has requested to amend the detailed specification of item code 8012: Surgical Suture (Absorbable, Synthetic) 1/2 Cir Rb, Niddle 20mm, Length 70cm.	The specification is hereby amended as:- Surgical Suture (Absorbable, Synthetic) 1/2 Cir Rb, Needle 20mm, Length 70cm, USP 3/0 Needle Length: 20 mm, Suture Length: 70 cm, Synthetic Braided, Absorbable: 56 - 70 Days, Suture Material: Polyglactin 910, Needle Description: 20 mm, 1/2 Circle Round Body Needle, Coating: Calcium Stearate and Polyglactin 370, USP 3/0.
6.	Annexure -XII, Clause 18 (M): Detailed specification of Item	Bidder has requested to amend the detailed specification of item code: 8027: Silk Suture (3/8 Cir Rb needle 16mm, Length 76 cm), USP 4/0	The specification is hereby amended as:- Silk Suture (3/8 Cir Rb needle 16mm, Length 76 cm), USP 4/0 Needle Description: 3/8 Circle RB Needle Dimension: 16mm Suture Type and Length: Black Braided 76 cm, USP 4/0, Silk Non- Absorbable Suture.
7.	Annexure -XII, Clause 18 (M): Detailed specification of Item	Bidder has requested to amend the detailed specification of item code: 8034: Polyamide (3/8 Cutting Edge Needle, Double Arms Needle 6 mm, Suture Length 35-42 cm Size 10/0	The specification is hereby amended as:- Polyamide (3/8 Cutting Edge Needle, Double Arms Needle 6 Mm, Suture Length 35-42 cm Size 10/0 Synthetic Monofilament, Absorption Profile: Non-absorbable, Suture Type: Synthetic Monofilament, Suture Material: Nylon. Needle Length: 6mm Suture Length: 35-42 cm, Needle Description: 6 mm, 3/8 Cutting Edge Needle, Double Arms.
8.	Annexure -XII, Clause 18 (M): Detailed specification of Item	Bidder has requested to amend the detailed specification of item code: 8035: Polypropylene Suture (1/2 Cir Rb, 13mm Needle, Suture Length 75cm, double arm), USP 5/0	The specification is hereby amended as:- Polypropylene Suture (1/2 Cir Rb, 13mm Needle, Suture Length 75cm, double arm), USP 5/0. Polypropylene, Synthetic Monofilament, Absorption Profile: Non-absorbable,

			<p>Suture Type: Synthetic Monofilament, Suture Material: Polypropylene. Needle Length: 13mm Suture Length: 75 cm, Needle Description: 13 mm, 1/2 CIR RB Needle, Double Arms, USP 5/0. CE certification</p>
9.	Annexure -XII, Clause 18 (M): Detailed specification of Item	<p>Bidder has requested to amend the detailed specification of item code: 8038: Polypropylene Suture (3/8 Cir Rb, 16mm Needle, Suture Length 70cm), USP 5/0</p>	<p>The specification is hereby amended as:-</p> <p>Polypropylene Suture (3/8 Cir Rb, 16mm Needle, Suture Length 70cm, USP 5/0 Needle Length: 16mm, Suture Length: 70cm, Synthetic Monofilament, Non-Absorbable, Suture Material: Polypropylene, Needle Description: 8mm, 3/8 Circle RB, USP 5/0. CE certification</p>
10.	Annexure -XII, Clause 18 (M): Detailed specification of Item	<p>Bidder has requested to amend the detailed specification of item code: 8039: Polypropylene Suture (1/2 Cir Rb, 30mm Needle, Suture Length 90cm), USP 2/0</p>	<p>The specification is hereby amended as:-</p> <p>Polypropylene Suture (1/2 Cir Rb, 30mm Needle, Suture Length 90cm), USP 2/0 Needle Length: 30mm, Suture Length: 90cm, Synthetic Monofilament, Non - Absorbable, Suture Material: Polypropylene, Needle Description: 30mm, 3/8 Circle RB, USP 2/0.</p>
11.	Annexure -XII, Clause 18 (M): Detailed specification of Item	<p>Bidder has requested to amend the detailed specification of item code: 8042: Polypropylene Suture (1/2 Tapercut, 17mm Double Needle, Suture Length 70cm), USP3/0</p>	<p>The specification is hereby amended as:-</p> <p>Polypropylene Suture (1/2 Tapercut, 17mm Double Needle, Suture Length 70cm), USP3/0 Polypropylene, Synthetic Monofilament, Absorption Profile: Non-absorbable, Suture Type: Synthetic Monofilament, Suture Material: Polypropylene Needle Length: 17mm Suture Length: 70 cm, Needle Description: 17 mm, 1/2 TAPERCUT Needle, Double Arms, USP3/0. CE certification</p>

12.	Annexure -XII, Clause 18 (M): Detailed specification of Item	Bidder has requested to amend the detailed specification of item code: 8044: Polypropylene Suture (1/2 Cir Rb, 30mm Needle, Suture Length 90cm) double arm, USP 1/0	The specification is hereby amended as:- Polypropylene Suture (1/2 Cir Rb, 30mm Needle, Suture Length 90cm) double arm, USP 1/0 Polypropylene, Synthetic Monofilament, Absorption Profile: Non-absorbable, Suture Type: Synthetic Monofilament, Suture Material: Polypropylene. Needle Length: 30mm Suture Length: 90 cm, Needle Description: 30mm, 1/2 CIR RB Needle, Double Arms, USP 1/0. CE certification
13.	Annexure -XII, Clause 18 (M): Detailed specification of Item	Bidder has requested to amend the detailed specification of item code: 8048: Polypropylene Suture (3/8 Cir Rb, 13mm Needle, Suture Length 90cm) double arm, USP 6/0	The specification is hereby amended as:- Polypropylene Suture (3/8 Cir Rb, 13mm Needle, Suture Length 90cm) double arm, USP 6/0 Needle Description: 3/8 Cir RB Needle Dimension: 13mm, length 90 cm, USP 6/0 synthetic absorbable sterile Surgical material: Polypropylene, CE certification
14.	Annexure -XII, Clause 18 (M): Detailed specification of Item	Bidder has requested to amend the detailed specification of item code: 8052: Polypropylene Suture (1/2 Cir Rb, Reverse Cutting, 45mm Needle, Suture Length 100cm), USP 1	The specification is hereby amended as:- Polypropylene Suture (1/2 Cir Rb, Reverse Cutting, 45mm Needle, Suture Length 100cm), USP 1 Polypropylene, Synthetic Monofilament, Absorption Profile: Non-absorbable, Suture Type: Synthetic Monofilament Needle, Needle Description: 1/2 Circle reverse cutting Needle Dimension: 45mm, Length 100 cm, USP 1, Non- Absorbable Suture. CE certification
15.	Annexure -XII, Clause 18 (M): Detailed specification of Item	Bidder has requested to amend the detailed specification of item code: 8056: Polypropylene Suture (1/2 Circle, Tapercut, 17mm Needle, Suture Length 90cm, double arm), USP 3/0	The specification is hereby amended as:- Polypropylene Suture (1/2 Circle, Tapercut, 17mm Needle, Suture Length 90cm, double arm), USP 3/0 Suture Material: Polypropylene, Needle Description: 17mm, 1/2 Circle Tapercut, Suture Length 90cm double arm, USP 3/0, Synthetic, Non - Absorbable. CE certification

16.	Annexure -XII, Clause 18 (M): Detailed specification of Item	Bidder has requested to amend the detailed specification of item code: 8058: Polybutylate/ Silicon Coated Polyester Braided Green/ Blue (1/2 Cir Tapercut, 17 Mm Double Needle, Suture Length 75 Cm)size 4/0	The specification is hereby amended as:- Polybutylate/ Silicon Coated Polyester Braided Green/ Blue (1/2 Cir Tapercut, 17 Mm Double Needle, Suture Length 75 cm), Size 4/0 Polybutylate/ silicon, Synthetic Monofilament, Absorption Profile: Non-absorbable, Suture Type: Synthetic Monofilament Suture Type: Synthetic Braided, Absorption Profile: Non-Absorbable Suture, Polybutylate/ Silicon Coated Polyester Braided Green/ Blue (1/2 Cir Tapercut, 17 Mm Double Needle, Suture Length 75 cm) size 4/0 Suture Material: Polyester - Poly (ethylene terephthalate), Coating: Polybutylate/ Wax/ Silicone.
17.	Annexure -XII, Clause 18 (M): Detailed specification of Item	Bidder has requested to amend the detailed specification of item code: 8059: Polybutylate Coated polyester Braided White (1/2 Cir Tapercut, 17 Mm Double Needle, Suture Length 90 Cm)size 2/0	The specification is hereby amended as:- Polybutylate Coated Polyester Braided White (1/2 Cir Tapercut, 17 Mm Double Needle, Suture Length 90 Cm) size 2/0 Polybutylate/ silicon, Synthetic Monofilament, Absorption Profile: Non-absorbable, Suture Type: Synthetic Mono filament Suture Type: Synthetic Braided, Absorption Profile: Non-Absorbable Suture Polybutylate Coated Polyester Braided White (1/2 Cir Tapercut, 17 Mm Double Needle, Suture Length 90 Cm) size 2/0 Suture Material: Polyester - Poly (ethylene terephthalate), Coating: Polybutylate/ Wax/ Silicone.
18.	Annexure -XII, Clause 18 (M): Detailed specification of Item	Bidder has requested to amend the detailed specification of item code: 8060: Polybutylate / Silicon Coated polyester Braided Green / Blue (1/2 Cir Tapercut,17 Mm Double Needle, Suture Length 90 Cm) size 2/0,	The specification is hereby amended as:- Polybutylate / Silicon Coated Polyester Braided Green/ Blue (1/2 Cir Tapercut, 17 Mm Double Needle, Suture Length 90 Cm) size 2/0, Polybutylate/ silicon, Synthetic Monofilament, Absorption Profile: Non-absorbable, Suture Type: Synthetic Mono filament Suture Type: Synthetic Braided, Absorption Profile: Non-Absorbable Suture Polybutylate/ Silicon Coated Polyester Braided Green/ Blue (1/2 Cir

			<p>Tapercut, 17 Mm Double Needle, Suture Length 90 Cm) size 2/0,</p> <p>Suture Material: Polyester - Poly (ethylene terephthalate),</p> <p>Coating: Polybutylate/ Wax/ Silicone.</p>
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Part B:

S. No.	Tender Clause / Reference	Query / Suggestion	Clarification / Amendment
1.	Tender clause 3. K on page 10 of the tender document.	Bidders have raised their queries in reference to the eligibility criteria under clause no. 3.K to relax/ reduce the requirement of average turnover for consecutive three of the last four financial years i.e., 2019-20, 2020-21, 2021-22 & 2022-23 not less than 25 Crores (Twenty-Five Crore).	<p><u>No change</u></p> <p><i>Tender condition prevails.</i></p>
2.	Tender clause 3. K on page 10 of the tender document.	Bidders have requested to include turnover of financial year 2023-24 under tender clause 3.K	<p>The tender clause 3.K is hereby amended and authorized. The clause may be read as follows:</p> <p>Copies of the Audited Balance Sheet, Profit and Loss statement showing details of their annual average turnover for consecutive three of the last four financial years i.e., 2020-21, 2021-22, 2022-23 & 2023-24 shall not be less than 25 Crores (Twenty-Five Crore). Details shall be provided as per Annexure IV. Self-attested copies are to be submitted along with original copy of Annexure-IV.</p>
3.	Annexure -XII, Clause 18 (M): Detailed Specification of Item	Bidder has requested to amend and relax the requirement of 'properly folded in paper' in detailed specification of item code 6006: Rubber Examination Gloves Non-sterile (Small) & 6007: Rubber Examination Gloves Non-sterile (Medium).	<p>The amendment in detailed specification of item code 6006 & 6007 is hereby authorized as follows:</p> <p>Rubber examination gloves made of natural rubber latex. Made of natural rubber Latex, without tear, Free of holes, with Acceptable Quality Level (AQL) of 1.5 or less Tensile strength as per EN 455-2. Powder-free. Should Conform to IS 13422. ISI marked/ CE certified/ FDA.</p>
4.	Tender clause 4. GENERAL CONDITIONS: C: note on page 14 of tender document.	Bidder has requested to relax the detailed specification of Item Code– 8121, Glucometer test Strips must be compatible with the existing PMBI Glucometer i.e., DC – 8122, Digital Glucometer.	<p><u>No change</u></p> <p><i>Tender condition prevails.</i></p>

5.	Annexure -XII, Clause 18 (M): Detail Specification of Item	Bidder has requested to amend the detailed specification and packaging standard of item code 7001: Hot Water Bottle (Small) as <u>1's in sealed poly pack</u> instead of 1's in sealed poly pack and in mono carton.	The unit size of item code 7001 is hereby authorized as follows: <u>1's in sealed poly-pack.</u>
6.	Annexure -XII, Clause 18 (M): Detail Specification of Item	Bidder has requested to amend the detailed specification and packaging standard of item code 8088: Walking stick Quadripod as <u>1's in sealed poly pack</u> instead of 1's in sealed poly pack and in mono carton.	The unit size of item code 8088 is hereby authorized as follows: <u>1's in sealed poly-pack.</u>
7.	Annexure -XII, Clause 18 (M): Detail Specification of Item	Bidder has requested to amend the detailed specification of item code 8135: Breathing Exerciser (3 Chambers)	<u>No change</u> <i>Tender condition prevails.</i>
8.	Annexure -XII, Clause 18 (M): Detail Specification of Item	Bidder has requested to amend the detailed specification of item code 8132: Plastic Bedpan	<u>No change</u> <i>Tender condition prevails.</i>
9.	Tender clause 3. H on page 10 of the tender document.	Bidder has requested to amend the tender clause and relax the submission of QMS certificate issued by National Accreditation Board for Certification Bodies (NABCB).	<u>No change</u> <i>Tender condition prevails.</i> However, it is to clarify that bidder must submit the Quality Management System (QMS) certificate issued on behalf of the manufacturer by any accredited/ notified body by National Accreditation Board for Certification Bodies (NABCB), India. The QMS certificate should remain valid till the last date of submission of tender.
10.	Tender clause 19. K at page 24 of tender document.	Bidder has requested to amend and relax the tender clause 'Bidder must supply the items with minimum 36 months shelf life. Bidders must declare the required shelf-life detail in Annexure XIII' for item code 8121: Glucometer Test Strip.	The amendment is hereby authorized and may be read as: Bidder shall supply item code 8121: Glucometer Test Strip with shelf life not less than 24 months.
11.	Annexure -XII, Clause 18 (M): Unit Size	Bidder has requested to amend the unit size of item code 8121: Glucometer Test Strip as <u>'25 Strips in HDPE container with silica'</u> instead of 25 Strips in	The amendment in unit size of item code 8021 is hereby authorized and may be read as:

		HDPE Screw cap container with silica pouch as required.	25 Strips in airlock HDPE container with silica.
12.	Annexure -XII, Clause 18 (M): Detail Specification of Item	Bidder has requested to amend the detailed specification of item code 8012: Surgical Suture (Absorbable, Synthetic) 1/2 Cir Rb, Niddle 20mm, Length 70cm.	The amendment in detailed specification of item code 8012 is hereby authorized and may be read as: Item code 8012: Surgical Suture (Absorbable, Synthetic) 1/2 Cir Rb, Needle 20mm, Length 70cm. Detailed specification: Needle Length: 20 mm, Suture Length: 70 cm, Synthetic Braided, Absorbable: 56 - 70 Days, Suture Material: Polyglactin 910, Needle Description: 20 mm, 1/2 Circle Round Body Needle, Coating: Calcium Stearate and Polyglactin 370.
13.	Annexure -XII, Clause 18 (M): Detail Specification of Item	Bidder has requested to amend the detailed specification of item code 8027: Silk Suture (3/8 Cir Rb needle 16mm, Length 76 cm), USP 4/0.	<u>No change</u> <i>Tender condition prevails.</i>
14.	Annexure -XII, Clause 18 (M): Detailed specification of Item	Bidder has requested to amend the generic name and detailed specification of item code 8034: Polyamide (3/8 Cutting Edge Needle, Double Arms Needle 6 mm, Suture Length 35-42 cm Size 10/0	<u>No change</u> <i>Tender condition prevails.</i>
15.	Annexure -XII, Clause 18 (M): Detailed specification of Item	Bidder has requested to amend the detailed specification of item code 8035: Polypropylene Suture (1/2 Cir Rb, 13mm Needle, Suture Length 75cm, double arm), USP 5/0	The amendment in detailed specification of item code 8035 is hereby authorized and may be read as: Polypropylene Suture (1/2 Cir Rb, 13mm Needle, Suture Length 75cm, double arm) Polypropylene, Synthetic Monofilament, Absorption Profile: Non-absorbable, Suture Type: Synthetic Monofilament, Suture Material: Polypropylene. Needle Length: 13mm Suture Length: 75 cm, Needle Description: 13 mm, 1/2 CIR RB Needle, Double Arms. CE certification
16.	Annexure -XII, Clause 18 (M): Detailed specification of Item	Bidder has requested to amend the detailed specification of item code 8042: Polypropylene Suture (1/2 Taper cut, 17mm Double Needle, Suture Length 70cm), USP3/0	The amendment in detailed specification of item code 8035 is hereby authorized and may be read as: Polypropylene Suture (1/2 Taper cut, 17mm Double Needle, Suture Length 70cm)

			Polypropylene, Synthetic Monofilament, Absorption Profile: Non-absorbable, Suture Type: Synthetic Monofilament, Suture Material: Polypropylene Needle Length: 17mm Suture Length:70 cm, Needle Description: 17 mm, 1/2 TAPERCUT Needle, Double Arms. CE certification
17.	Annexure -XII, Clause 18 (M): Detailed specification of Item	Bidder has requested to amend the detailed specification of item code 8044: Polypropylene Suture (1/2 Cir Rb, 30mm Needle, Suture Length 90cm) double arm, USP 1/0	<p>The amendment in detailed specification of item code 8035 is hereby authorized and may be read as:</p> <p>Polypropylene Suture (1/2 Cir Rb, 30mm Needle, Suture Length 90cm) double arm</p> <p>Polypropylene, Synthetic Monofilament, Absorption Profile: Non-absorbable, Suture Type: Synthetic Monofilament, Suture Material: Polypropylene. Needle Length: 30mm Suture Length:90 cm, Needle Description: 30mm, 1/2 CIR RB Needle, Double Arms. CE certification</p>
18.	Annexure -XII, Clause 18 (M): Generic Name of Item	Bidder has requested to amend the generic name and detailed specification of item code 8052: Polypropylene Suture (1/2 Cir Rb, Reverse Cutting, 45mm Needle, Suture Length 100cm), USP 1	<p><u>No change</u></p> <p><i>Tender condition prevails.</i></p>
19.	Annexure -XII, Clause 18 (M): Generic Name of Item	Bidder has requested to amend the generic name and detailed specification of item code 8059: Polybutylate Coated polyester Braided White (1/2 Cir Taper cut, 17 Mm Double Needle, Suture Length 90 Cm)size 2/0	<p><u>No change</u></p> <p><i>Tender condition prevails.</i></p>
20.	Tender Clause 3. F at page 9 of tender document	Bidder has requested to relax the submission of three-year old market standing certificate for each quoted product.	<p><u>No change</u></p> <p><i>Tender condition prevails.</i></p>
21.	Tender clause 3. J at page 10 of tender document	Bidder has requested to relax the tender clause no. 3. J, the maximum production capacity certificate for drug items which is mandated to be issued by the concerned licensing authority and requested to accept it from C.A/ C.S.	<p><u>No change</u></p> <p><i>Tender condition prevails.</i></p> <p>However, it is to clarify that as per tender clause 3.J 'For Products falling under Drug item/ Medical Devices/ Consumable/ Surgical as per Medical Devices Rules 2017/ Drugs & Cosmetics Act 1940, Production Capacity Certificate shall be issued from the concerned licensing Authority while for quoted non-drug products tenderer must declare their Maximum Production Capacity (item wise) in Annexure XIV</p>

			duly authorized from C.A/ C.S/ Authorized Signatory on company letter head'
22.	Annexure -XII, Clause 18 (M): Detailed specification of Item	Bidder has requested to amend the detailed specification of item code 8128: Digital Medical Thermometer (100% Mercury Free) with Storage Case as <u>Safety and Product Standards shall be of ISO/ IEC standard</u> instead of 'Safety and Product Standards shall be of ISO standard' as required in tender.	<u>No change</u> <i>Tender condition prevails.</i>
23.	Tender clause 3. E. c. (i) at page 9 of tender document	Bidder has raised query regarding required documents to be submitted against the tender clause 3. E. c. (i) <i>'The medical device shall confirm to the standards laid down by the Bureau of Indian Standards established under section 3 of the Bureau of Indian Standards Act, 1985 (63 of 1985) or as may be notified by the Ministry of Health and Family Welfare in the Central Government, from time to time'.</i>	It is to clarify that as per tender clause 3.D, 'For items covered under BIS, tenderer should have BIS certificate. In case, the products are covered under Drugs and Cosmetics Act 1940/ Medical Device Act 2017, the tenderer shall have valid manufacturing licence duly licensed by licensing authorities.'
24.	Annexure -XII, Clause 18 (M): Detailed specification of Item	Bidder has requested to amend and accept QMS ISO 13485 for quality certification against item code 6045, 6046, 6047, 6048 & 6049: Ryle's Tube/ Nasogastric Tube	The amendment in detailed specification is hereby authorized and may be read as: Item code 6045: Ryle's Tube/Nasogastric Tube (Size 10) Soft kink, resistance PVC tubing for atraumatic intubation. Closed distal end should be coned with radio opaque Material for accurate intubation. Four lateral eyes for greater efficiency. Radio Opaque Line. Marking at 50, 60,70 cm from trip. Color coded funnel. With luer connector / closure. Length 105 cm. CE/ ISO certified Item code 6046: Ryle's Tube/Nasogastric Tube (Size 12) Soft kink, resistance PVC tubing for atraumatic intubation. Closed distal end should be coned with radio opaque Material for accurate intubation. Four lateral eyes for greater efficiency. Radio Opaque Line. Marking at 50, 60,70 cm from trip. Color coded funnel. With luer connector / closure. Length 105 cm. CE/ ISO certified



Item code 6047: Ryle's Tube/Nasogastric Tube (Size 14)
Soft kink, resistance PVC tubing for atraumatic intubation. Closed distal end should be coned with radio opaque Material for accurate intubation. Four lateral eyes for greater efficiency. Radio Opaque Line. Marking at 50, 60,70 cm from trip. Color coded funnel. With luer connector / closure. Length 105 cm. CE/ ISO certified

Item code 6048: Ryle's Tube/Nasogastric Tube (Size 16)
Soft kink, resistance PVC tubing for atraumatic intubation. Closed distal end should be coned with radio opaque Material for accurate intubation. Four lateral eyes for greater efficiency. Radio Opaque Line. Marking at 50, 60,70 cm from trip. Color coded funnel. With luer connector / closure. Length 105 cm. CE/ ISO certified

Item code 6049: Ryle's Tube/Nasogastric Tube (Size 18)
Soft kink, resistance PVC tubing for atraumatic intubation. Closed distal end should be coned with radio opaque Material for accurate intubation. Four lateral eyes for greater efficiency. Radio Opaque Line. Marking at 50, 60,70 cm from trip. Color coded funnel. With luer connector / closure. Length 105 cm. CE/ ISO certified

25.	Annexure -XII, Clause 18 (M): Detailed specification of Item	Bidder has requested to amend the detailed specification of item code 8101: Cervical Collar Soft (Large)	<p>The amendment in detailed specification is hereby authorized and may be read as:</p> <p>Made of high-density polyurethane foam, density not less than 18 kg/m³, reinforced with very thick LDPE sheet not less than 1.5mm with rounded edges and shaped to give a uniform mandible support. Nylon sewing thread 210/6.</p> <p>Eyelets: 3 in Number. Made up of virgin polypropylene diameter not less than 20 mm.</p> <p>Stockinette: Dermophillic and hypoallergenic blend of cotton and rayon which should be free from spinning, weaving and processing defects.</p> <p>Fasteners, Hook and Loop Tape: The tape shall have the minimum width of 5 cm and minimum overlap 2.5 cm. Expandity of the collar should be 5 cm.</p>
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			<p>Total Length: not less than 550 mm (excluding fasteners)</p> <p>Length between center of extreme eyelets: not less than 150 mm</p> <p>Width between crest: Not less than 125 mm</p> <p>Confirming to the standards of IS 11569</p>
26.	Annexure -XII, Clause 18 (M): Detailed specification of Item	Bidder has requested to amend the detailed specification of item code 8113: Hernia Belt (Small)	<p><u>No change</u></p> <p><i>Tender condition prevails.</i></p>
27.	Annexure -XII, Clause 18 (M): Detailed specification of Item	Bidder has requested to amend the detailed specification of item code 8116: IV Cannula Fixator (Medium 6cm x 5cm)	<p><u>No change</u></p> <p><i>Tender condition prevails.</i></p>
28.	Annexure -XII, Clause 18 (M): Detailed specification of Item	Bidder has requested to amend the detailed specification of item code 9046 : Cervical Collar - Hard (Medium)	<p>The amendment in detailed specification is hereby authorized and may be read as:</p> <p>Description: Made of High-density polyethylene sheet for rigid support confirming to Indian Standards, padded with foam leather Soft rexin, anatomically designed to immobilize and support the neck with height adjustment for perfect fitting. Perforated collar body to provide proper air ventilation. Adjustable in both circumference and height. Length of the collar shall be adjustable by means of Nylon hook and loop fastener, Strip thickness Not Less Than (NLT) 1.5 mm</p> <p>Product Dimension (in mm):- Product Length: NLT 410mm Product width in center: 80-100mm Nylon Loop Length: 155-175mm Nylon Hook Length: 55-75mm Nylon sewing thread 210/6 or Cotton sewing thread 60s/6 (100 dtex x 6) Collar shall be tailored neatly and shall be free from any manufacturing defects; collar shall be padded as per IS Specification</p>
29.	Annexure -XII, Clause 18 (M): Detailed specification of Item	Bidder has requested to amend the detailed specification of item code 9053 : Cervical Collar - Hard (Large)	<p>The amendment in detailed specification is hereby authorized and may be read as:</p> <p>Description: - Made of High-density polyethylene sheet for rigid support confirming to Indian Standards, padded with</p>



			<p>foam leather Soft rexin, anatomically designed to immobilize and support the neck with height adjustment for perfect fitting, Perforated collar body to provide proper air ventilation, Adjustable in both circumference and height. Length of the collar shall be adjustable by means of Nylon hook and loop fastener, Strip thickness Not Less Than (NLT) 1.5 mm.</p> <p>Product Dimension (in mm):- Product Length: NLT 450mm Product width in center: 82-102mm Nylon Loop Length: 168-188mm Nylon Hook Length: 65-85mm Nylon sewing thread 210/6 or Cotton sewing thread 60s/6 (100 dtex x 6)</p> <p>Collar shall be tailored neatly and shall be free from any manufacturing defects; collar shall be padded as per IS Specification</p>
30.	Annexure -XII, Clause 18 (M): Detailed specification of Item	Bidder has requested to amend the detailed specification of item code 5078: Dengue Test Kit	<p>The amendment in detailed specification is hereby authorized and may be read as:</p> <p>DENGUE ANTIGEN SELF-TEST KIT- Easy-to-use and qualitative detection of dengue through the presence of dengue virus antigens in human blood samples, immunochromatographic technology. Result Time: 15-20 minutes. Contains: Test kit, 1 Lancet, 2 nos. Alcohol Swab, Package insert • Storage- 2° C - 8° C. The product should comply with ISO 9001 ISO 13485 (QMS)/CE/USFDA. Each Lot should PASS the test from ICMR designated labs.</p>
31.	Annexure -XII, Clause 18 (M): Detailed specification of Item	Bidder has requested to amend the detailed specification of item code 8151: Adhesive wound dressings, 25cm x 10cm	<p>The amendment in detailed specification is hereby authorized and may be read as:</p> <p>Adhesive wound dressings 25cm x 10cm Consisting of breathable non-woven top layer and a low-adherent absorbent pad Size: 25cm x 10cm, Each dressing is individually wrapped and sterile. Sterilization is by ethylene oxide. CE/ ISO certified</p>

32.	Annexure -XII, Clause 18 (M): Detailed specification of Item	Bidder has requested to amend the measurement unit of circumference compression value as mm of Hg instead of cm mentioned in the tender against item code: 8182, 8183, 8184, 8185, 8186, 8187, 8188, 8189, 8190 & 8191: Vein Compression Stocking Knee length & Thigh length	The measurement unit of circumference compression value against each Vein Compression Stocking Knee length & Thigh length invited vide item codes: 8182, 8183, 8184, 8185, 8186, 8187, 8188, 8189, 8190 & 8191 in the tender is hereby amended as mm of Hg . The same may be illustrated as follows and it shall be applicable for all item codes mentioned above: e.g., Circumference Compression (mm of Hg) Ankle >30 mm of Hg Calf >40 mm of Hg Popliteal > 40 mm of Hg Lower Thigh >60 mm of Hg Upper Thigh >70 mm of Hg
33.	Annexure -XII, Clause 18 (M): Detailed specification of Item	Bidder has requested to amend the detailed specification of item code 8088: Walking Stick Quadri pod	The amendment in detailed specification is hereby authorized and may be read as: Durable, lightweight, rustproof, single telescopic height adjustable shaft made of high-grade aluminum alloy (corrosion resistant) with a Molded handgrip and branching into four tips. Confirming standards to IS 5145 Handle: Made of injection- molded polypropylene of grade MI3530 (e.g., injection-Molded polypropylene of grade MI3530). Offset shape design to position your weight directly over the shaft, increasing stability and putting less pressure on the wrists. Net length- Not less than 740-940 mm Shaft: Made of extruded anodized aluminum (recyclable). The shaft should be in two parts, telescopic in nature. Height adjustable mechanism to be made out of plaited mild steel/ stainless steel for high strength, low deformation and resistance to abrasion. The pin should be made of stainless steel, at least 6mm in diameter and electroplated to prevent corrosion. Clearance between sliding parts not to exceed 0.5mm. Net length- Not less than 740 mm extendable up to 940 mm. Tips: Non-slip and replaceable, made of PU/ PVC. Anti-rattle system to reduce noise made when walking. Net weight: not less than 800 g

34.	Annexure -XII, Clause 18 (M): Detailed specification of Item	Bidder has requested to amend the detailed specification of item code 8196: Heating pad (electrical)	The detailed specification shall be as per tender document, only amendment in size and fitting is authorized and may be seen as follows: Size: 34-35 cm X 26-27 cm <i>Fitting: The item shall be ergonomically designed to fit on the abdomen, back, thigh, shoulders, legs, waist etc.</i> Rest of the specifications remains unchanged as per the tender document.
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***Note:** If poly-pack is specified as primary packaging, the bidder shall ensure the Government guidelines and minimum thickness of the packaging shall be not less 120 microns [as per rules 4(1) (c) of Plastic Waste Management (PWM) Rules, 2016 (as amended)].

All other contents of tender document remain unaltered. Bidders are requested to quote their rates considering all the terms and condition of the tender document including Amendment no. 1 dated 14/08/2024, Amendment no. 2 dated 30/08/2024 and this Amendment no. 3 dated 04/09/2024.

Sd/-
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