

**PHARMACEUTICALS AND MEDICAL DEVICES BUREAU OF INDIA (PMBI)**  
**(Set up under the Department of Pharmaceuticals, Govt. of India)**  
8<sup>th</sup> Floor, Videocon Tower, Block E1, Jhandewalan Extension, New Delhi-110055

**Amendment No. 2**

**Ref. No: - PMBI/SURGICAL/RC-210/2023.**

**Dated: 26/07/2023**

**Subject: - Tender No. PMBI/SURGICAL/RC-210/2023 dated 15/06/2023 for Supply of Surgical/Consumables and Medical Devices to Pharmaceuticals and Medical Devices Bureau of India (PMBI).**

Pharmaceuticals and Medical Devices Bureau of India (PMBI) has invited e-Bids from the interested parties for “e- Tender for Supply of Surgical/ Consumables and Medical Devices for the year 2023-2025”, vide Notice Inviting e-Tender No.- PMBI/DRUG/RC-207/2023 dated 15/06/2023. 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](http://www.eprocure.gov.in) and PMBI Website; [www.janaushadhi.gov.in](http://www.janaushadhi.gov.in).

The following amendment in Tender Document is hereby authorized through Part-A and Part-B: -

**Part- A:**

S. No.	Tender Clause / Reference	Query / Suggestion	Clarification / Amendment
1.	<b>3. ELIGIBILITY CRITERIA (TECHNICAL BID - COVER “A”): (ii)</b>	Bidder has raised query in reference to the eligibility criteria under clause no. 3, that whether bidders submitting ‘Start-up certificate from Department of Industrial Policy and Promotion (DIPP)’ are exempted from submission of Market standing/ Past performance.	In this regard, it is clarified that bidders submitting valid Start-up certificate issued by Department of Industrial Policy and Promotion (DIPP) are exempted from submission of prior turnover and prior experience. Hence, Tender condition prevails.
2.	<b>Annexure -XII, Clause 18 (M): Detail Specification of Item</b>	One of the bidders have requested to amend the specification of DC-6035 as per actual market trends i.e., addition of integrated 2-way stop cock in the specification instead of Integrated 3-Way stop Cock which is further supported by other bidders as well.  They further requested the same amendment for DC 6036, 6037 and 6038	The amendment is hereby authorized as follow:  DC-6035 is hereby amended as: I.V Cannula (Sterile, Disposable), 18 G Sterile Disposable (Single Use) Teflon/ PTFE I.V. Cannula with Integrated 2-Way stop Cock having radio opaque catheter with CE certification. Size 18G, should conform to IS 10555

			<p>DC-6036 is hereby amended as: I.V Cannula (Sterile, Disposable), 20 G Sterile Disposable (Single Use) Teflon/ PTFE I.V. Cannula with Integrated 2-Way stop Cock having radio opaque catheter with CE certification. Size 20G, should conform to IS 10555 Standard</p> <p>DC-6037 is hereby amended as: I.V Cannula (Sterile, Disposable), 22 G Sterile Disposable (Single Use) Teflon/ PTFE I.V. Cannula with Integrated 2-Way stop Cock having radio opaque catheter with CE certification. Size 22G, should conform to IS 10555 Standard</p> <p>DC-6038 is hereby amended as: I.V Cannula (Sterile, Disposable), 24 G Sterile Disposable (Single Use) Teflon/ PTFE I.V. Cannula with Integrated 2-Way stop Cock having radio opaque catheter with CE certification. Size 24G, should conform to IS 10555 Standard</p>
3.	<b>3. ELIGIBILITY CRITERIA (TECHNICAL BID - COVER "A"): D</b>	Bidders have requested to clarify the requirement of BIS certification saying BIS certification are not being issued by BIS Authority. Few others have mentioned that BIS requirement may restrict the competition.	<p>After due deliberation, the committee has agreed to amend the part of the clause 3.D i.e.,</p> <p><b>For:</b> "For items covered under BIS, tenderer should have BIS certificate"</p> <p><b>Read as:</b> "For items covered under BIS, bidders shall comply to the guidelines of BIS and BIS certification shall be preferred for the same"</p> <p>However, whichever products in the tender are not falling under compulsory BIS certification shall be submitted under other mentioned optional certifications sought in the tender i.e., BIS/ CE/ USFDA certification.</p>
4.	<b>Annexure -XII, Clause 18 (M): Detail Specification of Item</b>	One of the bidders has requested for compulsion of IS 13422 certifications for Item code-6001, 6002 & 6003 and removal of CE certified/FDA to encourage Make in India.	Tender condition prevails.
5.	<b>Annexure -XII, Clause 18 (M): Detail Specification of Item</b>	For DC-8127, one of the attendees suggested that the material of the mask should not be restricted to only PVC material and TP material, LDPE shall also be allowed. They have further suggested to remove nose clip from the specification of DC-8127,	Tender condition prevails.

		highlighting that it may cause discomfort and rashes on the nose of patients.	
6.	<b>Annexure -XII, Clause 18 (M): Detail Specification of Item</b>	For DC-8131, intending bidder has requested to amend the weight of the product which is mentioned as Not less than 150g, whereas market standard is around 90-100g.	<u>Only the weight of the product is hereby amended as: Weight: Not less than 100 g.</u>  Other specifications remain unaltered.
7.	<b>Annexure -XII, Clause 18 (M): Detail Specification of Item</b>	For DC-8132, the intending bidder has requested to consider Polypropylene (PP) material besides virgin high grade ABS material. They further requested to amend the weight of the product Not less than 750gm (in tender) to 350-400gm and size of the product from 40 cm X 30 cm 9 cm to 38cm X 28cm X 6cm.	No change is authorized in the material and the product shall be Made of high virgin ABS material.  <u>The Weight of the product is here by amended as: Not less than 400g</u>  Other specifications remain unaltered.
8	<b>Annexure -XII, Clause 18 (M): Secondary Pack</b>	One of the intending bidders has requested to amend the Secondary pack under Annexure XII for Item Code- 5020 and 5021 as 1's X 6 in mono-carton and 1's X 4 in mono-carton instead of 1's X 12 in mono-carton respectively.	The following amendment in the secondary pack is hereby authorized as: For item code -5020, the secondary pack is amended as 1's X 6 in mono-carton and for item code -5021, the secondary pack is amended as 1's X 4 in mono-carton.
9	<b>Annexure -XII, Clause 18 (M): Detail Specification of Item</b>	For Item code 5116, IV Cannula Fixator (Medium 6cm x 5cm), one of the intending bidders has raised their query to clarify whether the product is Elastic Adhesive bandage type IV dressing or Transparent PU Film IV Dressing with High MVTR.	It is to clarify all the bidders that Item code 5116, IV Cannula Fixator (Medium 6cm x 5cm) is Elastic Adhesive bandage type IV dressing.
10	<b>Annexure -XII, Clause 18 (M): Secondary Pack</b>	One of the intending bidders has requested to amend the Secondary pack for Item Code-8123 & 8125 as 5 cm x 5-meter x 6 rolls in mono carton & 1.25cm x 5-meter x 24 rolls in mono carton respectively instead of 1's X 12 in mono carton in tender.	The following amendment in the secondary pack is hereby authorized as: For item code -8123, the secondary pack is amended as 1's X 6 Roll in mono-carton and for item code -8125, the secondary pack is amended as 1's X 24 Roll in mono-carton.
11	<b>Annexure -XII, Clause 18 (M): Unit Size</b>	One of the intending bidders has requested to consider the Unit Size for Item Code-8181 and requested to amend the packaging as "1's in peelable paper poly or paper to paper pouch" instead of "1's in peelable Aluminium foil pack".	<u>The secondary pack is hereby amended as</u> 1's in peelable paper to Poly pack.

12	<b>Annexure -XII, Clause 18 (M): Unit Size</b>	Prospective bidder has requested to amend Unit size for Item code 5083 as “100’s in PP jar” instead of “100’s in PET jar”.	<u>The following amendment in the Unit size is hereby authorized as: “100’s in PP jar”.</u>
13	<b>Annexure -XII, Clause 18 (M): Detail Specification of Item</b>	For Item code-8155, amendment in the specification of item is requested by one of the participants i.e., <i>“Made from extra soft and ultra fine spun lace fabric. Alcohol free, paraben free, SLS free, hypoallergic to infant skin. <u>Infused with Aloe vera and Vitamin E (Veg origin). Mild fragrance. Microwaveable.</u></i> Size: 200 mm X 150 mm per wipe pH: 4.5 -6, Mass: > 36 g/m2, Moisture content: > 90 % by 98 % demineralized water. Breaking Strength: Machine direction (wet): > 30 N/min Cross direction (wet): > 2.5 N/min  <b><i>Due to interchange in the specification with item code 8156 the amendment request is accepted.</i></b>	<u>Tender specification for Item code 8155 is hereby amended as:</u>  <u>Made from extra soft and ultra fine spun lace fabric. Alcohol free, paraben free, SLS free, hypoallergic to infant skin. Infused with Aloe vera and Vitamin E (Veg origin). Mild fragrance. Microwaveable.</u> Size: 200 mm X 150 mm per wipe pH: 4.5 -6, Mass: > 36 g/m2, Moisture content: > 90 % by 98 % demineralized water. Breaking Strength: Machine direction (wet): > 30 N/min Cross direction (wet): > 2.5 N/min.
14	<b>Annexure -XII, Clause 18 (M): Detail Specification of Item</b>	For Item code-8156, amendment is requested in the specification of item as Made from extra soft and ultra fine spun lace fabric. Alcohol free, paraben free, SLS free, hypoallergic to infant skin. Infused with 2% Chlorhexidine, Aloe vera and Glycerine, Mild fragrance. Size: 240 mm X 290 mm per wipe pH: 4.5 -6, Mass: > 36 g/m2, Moisture content: > 90 % by 98 % demineralized water. Breaking Strength: Machine direction (wet): > 30 N/min Cross direction (wet): > 2.5 N/min  <b><i>Due to interchange in the specification with item code 8155 the amendment request is accepted.</i></b>	<u>Tender specification for Item code 8156 is hereby amended as</u> <u>Made from extra soft and ultra fine spun lace fabric. Alcohol free, paraben free, SLS free, hypoallergic to infant skin. Infused with 2% Chlorhexidine, Aloe vera and Glycerine. Mild fragrance.</u> <u>Size: 240 mm X 290 mm per wipe pH: 4.5 -6, Mass: &gt; 36 g/m2,</u> <u>Moisture content: &gt; 90 % by 98 % demineralized water.</u> <u>Breaking Strength: Machine direction (wet): &gt; 30 N/min Cross direction (wet): &gt; 2.5 N/min.</u>
15	<b>Annexure -XII, Clause 18 (M): Generic Name of Item</b>	The Generic Name of the Item Code 9045 is noted with typographical error as “Insulting/Medicine Cooling Case”	<u>Tender specification for Item code 9045 is hereby amended as</u> <u>“Insulin/Medicine Cooling Case”</u>

#### **Part-B:**

I. For the terms/content in tender on Page 4, Sl. No. 6 ‘**Earnest Money Deposit/Bid Security Declaration**’ of TABLE OF CONTENTS, On Page 5, Sl. No. 42 ‘**ANNEXURE - X (Format of Bid Security Declaration)**’ of TABLE OF CONTENTS and On Page 34, Sl. No. 2 ‘**Bid Security declaration on non-judicial stamp paper as per ANNEXURE-III (Clause 3. A & 6. A)**’ of Annexure I (Check list) shall be read as-

***'Earnest Money Deposit, CONTENTS'ANNEXURE - X (Format for submission of Earnest Money Deposit (EMD)) and EMD Rs. 1,00,000/- (One lakhs) in the form of Bank Guarantee or National Electronic Fund Transfer (NEFT) or Bankers Cheque or Demand Draft or PMBI/DRUG/RC-209/2023 Page: 32/74 BG as per ANNEXURE-III (Clause 3. A & 6. A), respectively.***

**II. ANNEXURE X- DECLARATION OF LOCAL CONTENT** is here by stands omitted. It shall be read under **ANNEXURE- XVI.**

**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 10/07/2023 and this Amendment no. 2 dated 26/07/2023.**

Sd/-  
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