

#### **BID BULLETIN NO. 2**

05 January 2024

### PROCUREMENT OF BILATERAL TUBAL LIGATION KIT IB NO. 2024-124

This Bid Bulletin is being issued to announce the new schedule of Submission and Opening of Bids previously set last 20 December 2023, amend or modify the bidding documents posted in the PhilGEPS and DOH websites for the above-mentioned project, and to respond to Prospective Bidders (PBs) inquiries. This Bid Bulletin will form an integral part of the bidding document. Listed below are the corresponding modifications/changes:

#### 1. New Schedule of Activity

A otivity	From	To	Venue	
Activity	Date/Time	Date/time	venue	
Submission and Opening of Bids	20 December 2023 9:00 AM	17 January 2024 9:00 AM	COBAC Conference Room, Ground Floor, Bldg. No. 6, Department of Health, Sta. Cruz, Manila, and/or through video conferencing or webcasting via Cisco Webex	

#### 2. Response to Prospective Bidders' (PBs) inquiry:

			End-User Unit's
Bidder	Particular	Inquiry	(EUU) /COBAC
			Response
Surgicom Trading Corp.	Section II. Instructions to	Requesting for adjustment on the Completed contract from	Granted.
Truding Corp.	Bidder	two (2) years to five (5).	
	Section VI. Schedule of Requirements	Requesting for adjustment in the delivered calendar days from Sixty (60) calendar days to One Hundred Fifty (150).	Please see attached revised Schedule of Requirements.
	Section VII. Technical Specifications	<ul> <li>4. Graves Vaginal Speculum: To consider Weight: 159-175 grams.</li> <li>5. Sponge Forceps (Ovum forceps) Straight:</li> </ul>	Please see attached revised Technical Specifications.
		To consider Weight: 95-100 grams.  6. Apelo Retractors:	

Bidder	Particular	Inquiry	End-User Unit's (EUU) /COBAC Response
		To consider Weight — Short: at least 25 grams	
		To consider Thickness: <b>0.7 to 1.2mm</b>	
		7. Uterine Elevator: To consider Weight: 65-72 grams	
		12. Instrument tray/container with covert To remove the word "with cover"	
		To consider Weight: 615-630 grams	
		To consider Thickness: 0.7-1.0mm	
		13. Instrument cover with handle:	
		To consider Thickness: 0.7-1.0 mm	
		To consider Weight of cover: <b>350-360 grams</b>	
	Section VII. Technical Specifications – Additional Requirements	Clarifying if they can submit a Certificate of Medical Device Notification (CMDN) that was created and applied from another procuring entity. However, the contents of the kits vary per entity. Is it possible to submit the existing registered CMDN from another entity and additional CMDN to every item missing on the registered CMDN from another entity.	each missing item on the registered CMDN registered from another entity can be supported with individual CMDN respectively.
		Shelf life is not applicable for this item. Requesting for the deletion of this requirement.  To consider the suggested packaging Instruction:	Granted by the EUU. Please see attached revised Technical Specification.

Bidder	Particular	Inquiry	End-User Unit's (EUU) /COBAC Response
		One Stainless tray/container with cover and handle contains 1 BTL kit packed in a box.	
		1 pc tray with cover 8 pcs Kelly forceps 2 pcs needle holder 2 pcs blade holder	
		2 pcs tissue forceps 2 pcs Metzenbaum scissors 2 pcs sponge forceps 2 pcs allis forceps	
		2 sets apelo retractors 2 pcs speculum 2 pcs uterine elevator 2 pcs kidney basin	
		For deletion of Date of Manufacture, Date of Expiry, and Batch/Lot No. in the labeling instructions.	

#### 3. Section I. Invitation to Bid:

From	To
The DOH now invites bids for the procurement of the above-captioned project. Delivery of the Goods is required within the period specified under Section VI. Schedule of Requirements. Bidders should have completed, within two (2) years from the date of submission and receipt ofbids, a contract similar to the Project, equivalent to at least twenty-five percent (25%) of the ABC. The description of an eligible bidder is contained in the Bidding Documents, particularly, in Section II. Instructions to Bidders.	The DOH now invites bids for the procurement of the above-captioned project. Delivery of the Goods is required within the period specified under SECTION VI. Schedule of Requirements. Bidders should have completed, within Five (5) years from the date of submission and receipt of bids, a contract similar to the Project, equivalent to:  a) At least (2) similar contracts and the aggregate contract amounts should be equivalent to at least Fifty percent (50%) of the (ABC) as required above. b) The largest of these similar contracts must be equivalent to at least half of the Fifty percent (50%) of the ABC as required above.

#### 4. Section II. Instructions to Bidders:

ITB Clause	From	То
5.3	Pursuant to Section 23.4.1.3 of the 2016 Revised IRR of RA No. 9184, the Bidder shall have an SLCC that is at least one (1) contract similar to the Project the value of which, adjusted to current prices using the PSA's CPI, must be at least equivalent to:  a. For the procurement of Expendable Supplies: The Bidder must have completed a single contract that is similar to this Project, equivalent to at least twenty-five percent (25%) of the ABC.	Pursuant to Section 23.4.1.3 of the 2016 revised IRR of RA No.9184, the Bidder shall have an SLCC that is at least <b>two (2)</b> contract similar to the Project the value of which, adjusted to current prices using the PSA's CPI, must be at least equivalent to:  a For procurement where the Procuring Entity has determined, after the conduct of market research, that imposition of either (a) or (b) will likely result to failure of bidding or monopoly that will defeat the purpose of public bidding: The Bidder should comply with the following requirements:
		<ul> <li>i. Completed at least two (2) similar contracts, the aggregate amount of which should be equivalent to at least Fifty Percent (50%) of the ABC for this Project; and</li> <li>ii. The largest of these similar</li> </ul>
		contracts must be equivalent to at least half of the percentage of the ABC as required above.
10.2	The Bidder's SLCC as indicated in <b>ITB</b> Clause 5.3 should have been completed within <i>two</i> (2) <i>years</i> prior to the deadline for the submission and receipt of bids.	The Bidder's SLCC as indicated in <b>ITB</b> Clause 5.3 should have been completed within <i>five</i> (5) <i>years</i> prior to the deadline for the submission and receipt of bids.

#### 5. Section III. Bid Data Sheet:

ITB Clause	From	То
5.3	For this purpose, contracts similar to the Project shall be:	For this purpose, contracts similar to the Project shall be:
	a. Various laboratory/hospital and medical supplies	a. Various laboratory/hospital and medical supplies

ITB Clause	From	То
	b. completed within two (2) years prior to the deadline for the submission and receipt of bids.	b. completed within <b>five (5) years</b> prior to the deadline for the submission and receipt of bids

The revised Schedule of Requirements, Technical Specifications, and Checklist of Technical and Financial Documents are enclosed for the Prospective Bidders' reference and use.

All other provisions of the bidding documents which are not affected shall remain in force and in effect.

For guidance and information of all concerned

NESTOR F. SANTIAGO, JR., MD, MPHC, MHSA, CESO II

Undersecretary of Health COBAC-D Chairperson

### Section VI. Schedule of Requirements

The delivery schedule expressed as calendar days stipulates hereafter a delivery date which is the date of delivery to the project site.

Item Number	Description	Quantity	Total ABC (PhP)	Delivery Site	Delivered, Calendar Days
1	Bilateral Tubal Ligation Kit	1,000 kits	8,487,200.00	DOH Warehouse(s) within Metro Manila	One Hundred Twenty (120) calendar days upon receipt of approved Notice to Proceed (NTP).

Signature over Printed Name [date of signing]

In the capacity of: Duly authorized to sign bid for and on behalf of: [title or other appropriate designation]

[Name of Company]
[Complete office address]

[Contact No.] [Fax No.] [Email Address]

## **Technical Specifications**

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Department of		
TECHNICAL SPEC		1.000.7.0
Item No. 1   Bilateral Tubal Ligation Kit	Quantity / Unit	1,000 kits
Name of Manufacturer:	Country of Origin:	
Brand:		
Total ABC: <b>PhP8,487,200.00</b>		
PURCHASER'S SPECIFICATION	STATEMENT	OF COMPLIANCE
A. Detailed Technical Specifications:		
Bilateral Tubal Ligation (BTL) kit		
1. Kelly Forceps:		
a) Brand New		
b) Stainless Steel		
c) Straight: Length 6.0" – 6.5"		
d) Weight: 34-36 grams		
u) weight: 54-30 grains		
2. Needle Holder:		
A. Brand New		
B. Stainless Steel		
C. Length: 7"- 8"		
D. Weight: 63-65 grams		
3. Blade holder #3 (for blade no.10):		
A. Brand New		
B. Stainless Steel		
C. Weight: 27-29 grams		
4. Graves Vaginal Speculum:		
A. Brand New		
B. Bivalve Stainless Steel		
C. Size: Medium		
D. Weight: 159-175 grams		
5 Spange Foregons (Overm foregons) Straight.		
5. Sponge Forceps (Ovum forceps) Straight: A. Brand New		
B. Stainless steel		
C. Straight		
D. Length: 10 – 10.5 inches		
E. Weight: 95-100 grams		
6. Apelo Retractors:		
A. Brand New		
B. Stainless Steel		
C. Long 5.2"-5.5" 3"-3.2"1 ½ inch		
D. Weight – Long: at least 28 grams		
E. Short 5.2"-5.5" 2"-2.2"1 ½ inch		
L. SHOIL 3.2 3.3 2 2.2 1 /2 IIICII		

#### Republic of the Philippines Department of Health TECHNICAL SPECIFICATIONS Item No. 1 | Bilateral Tubal Ligation Kit Quantity / Unit 1,000 kits Name of Manufacturer: Country of Origin: Brand: Total ABC: PhP8,487,200.00 **PURCHASER'S SPECIFICATION** STATEMENT OF COMPLIANCE F. Weight – Short: at least 25 grams G. Width: 1/2 inch H. Thickness: 0.7 to 1.2 mm 7. Uterine Elevator: A. Brand New B. Stainless Steel C. With modified handle. Modified handle means flat solid handle. (Please see sample) D. Length: The length of entire uterine elevator = 12-13.5 inches, with the following measurement of each parts: a) Ball like tip of the uterine elevator = 4.0mm diameter b) Length of 1st curve from distal end of ball like to proximal portion of 50-55 mm c) Length of 2nd curve from distal end of 1st curve to proximal part of guard = 40-45 mm d) Thickness of 1st curve= 2mm e) Length of 3rd curve from distal part of guard=130-135 mm f) Diameter of guard = 20-25 mmh) Length of handle of uterine elevator = 75-80 mm i) Thickness of handle= 3mm E. Weight: 65-72 grams 8. Allis Forceps: A. Brand New B. Stainless Steel C. Length: 7.5 - 8 inches D. Weight: 50-53 grams 9. Kidney Basin: A. Brand New B. Stainless Steel C. 1.5 - 2 inches deep D. Length: 8 - 8.5 inches E. Width: 3.5 - 4.0 inches F. Weight: 150-160 grams

#### Republic of the Philippines Department of Health TECHNICAL SPECIFICATIONS Item No. 1 | Bilateral Tubal Ligation Kit Quantity / Unit 1,000 kits Name of Manufacturer: Country of Origin: Brand: Total ABC: PhP8,487,200.00 **PURCHASER'S SPECIFICATION** STATEMENT OF COMPLIANCE 10. Tissue Forceps: A. Brand New B. Stainless Steel C. Length: 6-6.5 inches D. Weight: 30-32 grams 11. Metzenbaum scissors: A. Brand New B. Stainless Steel C. Straight D. Length: 7-7.5 inches E. Weight: 55-58 grams 12. Instrument tray / container: A. Brand New B. Stainless Steel C. Length: 12-12.5 inches D. Width: 8-8.5 inches E. Height: 2-3 inches F. Weight: 615-630 grams G. Thickness=0.7 - 1.0mm 13. Instrument cover with handle: A. Brand New B. Stainless Steel C. Length: 12 - 13 inches D. Width: 8 - 9 inches E. Thickness: 0.7 - 1.0 mm F. Weight of cover: 350 - 360 grams **NOTE:** The word stainless steel and name of country where the product is made be imprinted in each instrument. Each item should have the DOH Logo laser

## B. Additional Requirements to be attached to Technical Specifications form arranged, numbered and tabbed as enumerated below:

imprinted on each item.

1. Valid and current Certificate Product Registration (CPR) or Certification of Medical Device Registration (CMDR) or Certificate of Medical Device Notification (CMDN) or Valid Extension issued by Philippine Food and Drug Administration (PFDA);

# Republic of the Philippines Department of Health TECHNICAL SPECIFICATIONS Item No. 1 Bilateral Tubal Ligation Kit Quantity / Unit 1,000 kits Name of Manufacturer: Country of Origin: Brand: Total ABC: PhP8,487,200.00 PURCHASER'S SPECIFICATION STATEMENT OF COMPLIANCE

The CPR must be valid for the entire period of the award. If the CPR is about to expire, the supplier must have submitted a copy of an application of renewal to the FDA at least 3 months before the expiry date (a copy of the expiring CPR which is stamped with an "Extension of Validity" shall be submitted as proof); [AO 2019-0041]

2. Valid and current License to Operate (LTO) for medical devices suppliers, distributors, and traders issued by Philippine Food and Drugs Administration (PFDA). *Provided, that the application for renewal was made timely as per DOH AO No. 2016-003:* 

#### In case of expired LTO, the following copies may be submitted:

- (i) expired LTO;
- (ii) application for renewal with FDA document tracking number; and,
- (iii) Official Receipt as proof of payment of renewal of LTO
- 3. Product Insert/Product Information or downloaded from the internet and other manufacturer's unamended sales literature, unconditional statements of specification and compliance issued by the manufacturer, samples, independent test data etc., as appropriate for cross-referencing statement of compliance to the technical specification in accordance to what is indicated in Technical Specifications;
- 4. Certification from the Manufacturer/Distributor/Importer/Wholesaler (as reflected in the Certificate of Product Registration of the product/s to be bid) that the Bidder is an authorized dealer or distributor of the product.
- 5. Manufacturers' Conformity with Good Manufacturing Practice or with ISO 13485.
- 6. Three (3) years warranty on craftsmanship upon acceptance.
- 7. Sworn Statement using the prescribed form.

#### C. Upon delivery the following shall be complied with:

#### 1. Packaging instructions:

- a) Standard packaging of the Supplier or
- b) One stainless tray/container with cover with handle contains 1 BTL kit packed in a box

#### **BTL Kits:**

- 1 pc tray with cover
- 8 pcs kelly forceps
- 2 pcs needle holder
- 2 pcs blade holder
- 2 pcs tissue forceps

# Republic of the Philippines Department of Health TECHNICAL SPECIFICATIONS Item No. 1 Bilateral Tubal Ligation Kit Quantity / Unit 1,000 kits Name of Manufacturer: Country of Origin: Brand: Total ABC: PhP8,487,200.00 PURCHASER'S SPECIFICATION STATEMENT OF COMPLIANCE

- 2 pcs metzenbaum scissors
- 2 pcs sponge forceps
- 2 pcs allis forceps
- 2 sets apelo retractors
- 2 pcs speculum
- 2 pcs uterine elevator
- 2 pcs kidney basin

#### 2. Labeling instructions:

- a) Standard labeling as approved by PFDA pursuant to Administrative Order No. 2016-0008.
- b) In addition to the labelling requirements of FDA:
  - i. On each **box** and **container** to indicate *items and quantities*, the following should be legibly imprinted or stickered with non-removable or permanent sticker/label that is binding and with residue and tearing, if removed:

Philippine Government Property – Department of Health **NOT FOR SALE** 

## D. Additional Requirements to be submitted by the Single/Lowest Calculated Bidder (S/LCB) as a part of post-qualification, to wit:

One (1) sample to be submitted for evaluation. The sample submitted and approved during the evaluation shall be the same to be delivered upon award contract

#### E. Product Recall & Disposal:

- 1. The Supplier must ensure the quality of products and if there will be problems in the quality, the Supplier will recall and replace the products distributed in the regions/hospitals/treatment hubs/RHU/HC/BHSS based on Guidelines on Product Recall, FDA Circular No. 2016-012;
- 2. In instances of product recalls due to failures of suppliers and manufacturers to comply with standards of safety and quality, the cost associated with proper disposal/ destruction, handling or pull out from health facilities where these products have already been distributed shall be borne by the supplier (subject to the latest policy for disposal) (DOH Administrative Order (AO) No. 2019-0041).

Signature over Printed Name [date of signing]

In the capacity of:

[title or other appropriate designation]

Duly authorized to sign bid for and on behalf of: [Name of Company]

[Complete office address]

[Contact No.] [Fax No.] [Email Address]

## **Checklist of Technical and Financial Documents Arranged numbered and tabbed as it appears below:**

#### I. TECHNICAL COMPONENT ENVELOPE

#### Class "A" Documents

Lega	ıl Docui	<u>ments</u>
	(a)	Valid PhilGEPS Registration Certificate (Platinum Membership) (all pages) in accordance with Section 8.5.2 of the IRR;
Tech	nical D	ocuments
	(b)	Statement of the prospective bidder of <b>All</b> its ongoing government and private contracts, including contracts awarded but not yet started, if any, whether similar or not similar in nature and complexity to the contract to be bid; <b>and</b>
	(c)	Statement of the bidder's <i>two</i> (2) <i>or more</i> completed contracts similar to the contract to be bid within <i>five</i> (5) years, <i>the aggregate amount should be equivalent to at least fifty percent</i> (50%) of the ABC.
		The largest of these similar contracts must be equivalent to at least half of the percentage of the ABC as required above; <b>and</b>
	(d)	Original copy of Bid Security. If in the form of a Surety Bond, submit also a certification issued by the Insurance Commission; or
		Original copy of Notarized Bid Securing Declaration; and
	(e)	Conformity with the Schedule of Requirements and Technical Specifications, which may include production/delivery schedule, manpower requirements, and/or aftersales/parts, if applicable; <b>and</b>
	(f)	Original duly signed Omnibus Sworn Statement (OSS); and if applicable, Original Notarized Secretary's Certificate in case of a corporation, partnership, or cooperative; or Original Special Power of Attorney of all members of the joint venture giving full power and authority to its officer to sign the OSS and do acts to represent the Bidder.
<u>Fina</u>	ncial D	ocuments
	(g)	The prospective bidder's computation of Net Financial Contracting Capacity (NFCC);
		or A committed Line of Credit from a Universal or Commercial Bank in lieu of its NFCC computation.

#### Class "B" Documents $\Box$ (h) If applicable, a duly signed joint venture agreement (JVA) in case the joint venture is already inexistence; duly notarized statements from all the potential joint venture partners stating that they will enter into and abide by the provisions of the JVA in the instance that the bid is successful. Other documentary requirements under RA No. 9184 (as applicable) (i) [For foreign bidders claiming by reason of their country's extension of reciprocal rights to Filipinos] Certification from the relevant government office of their country stating that Filipinos are allowed to participate in government procurement activities for the same item or product. (j) Certification from the DTI if the Bidder claims preference as a Domestic Bidder or Domestic Entity. II. FINANCIAL COMPONENT ENVELOPE (a) Original of duly signed and accomplished Financial Bid Form; and $\Box$ (b) Original of duly signed and accomplished Price Schedule(s). ADDITIONAL DOCUMENTARY REQUIREMENTS TO BE ATTACHED IN III. THE TECHNICAL SPECIFICATIONS FORM: (a) Valid and current Certificate Product Registration (CPR) or Certification of Medical Device Registration (CMDR) or Certificate of Medical Device Notification (CMDN) or Valid Extension issued by Philippine Food and Drug Administration (PFDA); The CPR must be valid for the entire period of the award. If the CPR is about to expire, the supplier must have submitted a copy of an application of renewal to the FDA at least 3 months before the expiry date (a copy of the expiring CPR which is stamped with an "Extension of Validity" shall be submitted as proof); [AO 2019-0041] $\Box$ (b) Valid and current License to Operate (LTO) for medical device suppliers, distributors and traders issued by PFDA. Provided, that the application for

#### In case of expired LTO, the following copies may be submitted:

renewal was made timely as per DOH AO No. 2016-003:

- (i) expired LTO;
- (ii) application for renewal with FDA document tracking number; and,
- (iii) Official Receipt as proof of payment of renewal of LTO

	(c)	Product Insert/Product Information or downloaded from the internet and other manufacturer's un-amended sales literature, unconditional statements of specification and compliance issued by the manufacturer, samples, independent test data etc., as appropriate for cross-referencing statement of compliance to the technical specification in accordance to what is indicated in Technical Specifications;
	(d)	Certification from the Manufacturer/Distributor/Importer/Wholesaler (as reflected in the Certificate of Product Registration of the product/s to be bid) that the Bidder is an authorized dealer or distributor of the product;
	(e)	Sworn Statement using the prescribed form.
	(f)	Manufacturers' Conformity with Good Manufacturing Practice or with ISO 13485.
	(g)	Three (3) years warranty on craftsmanship upon acceptance.
<b>Not</b> 1)	Please	refer to <a href="https://doh.gov.ph/sites/default/files/basic-page/COBAC-Sample-pdf">https://doh.gov.ph/sites/default/files/basic-page/COBAC-Sample-pdf</a> for the following requirements:
	b) Com c) Man d) Secr e) Spec f) State	rn Statement; aputation of NFCC; ufacturer's Authorization; etary's Certificate; ial Power of Attorney; ment of Ongoing Contracts; and ement of SLCC.
ŕ	a) Bid b) Price c) Bid	Form; e Schedule; Securing Declaration; and hibus Sworn Statement