Republic of the Philippines
Department of Health

CENTRAL OFFICE BIDS AND AWARDS COMMITTEE

BID BULLETIN NO. 3
07 December 2023

PROCUREMENT OF GLUCOMETER
IB NO. 2024-066

This Bid Bulletin is being issued to amend or modify the bidding document posted in the PhilGEPS and DOH websites, and to respond to the queries of Prospective Bidders (PBs), to clarify the issues and concerns raised during the Pre-Bidding Conference for the above-cited project. This Bid Bulletin shall form an integral part of the bidding documents. Listed below is the corresponding modification/change:

1. Changes in Section VII. Technical Specifications:

From	To
12. Packing List: 12.f. With replaceable battery, can last up to 18 moinths operation	12. Packing List: 12.f. With replaceable battery, can last up to 18 months operation **or approximately 1,000 times**
Additional Requirements 9. Certificate or Test Report that the product is compliant and tested with the emission and immunity requirements of EN/IEC.	Delete, refer to changes.

2. Response to the queries of Allied Hospital Supply International Corp. (AHSIC) and _ _ _ _ (SETC):

Name of Bidder	Query/Comment	Response
AHSIC	To submit proof of renewal in lieu of Valid and current Certificate of Product Registration (CPR) or Certificate of Medical Device Registration (CMDR) or Certificate of Medical Device Notification (CMDN) issued by Philippine Food and Drug Administration (PFDA). a. Application Form b. FDA Acknowledgement Receipt c. Proof of Payment	Not acceptable, no changes.
SETC	Technical Specifciations: 12. Packing List: 12.f with replacement battery, can last up to 18 months operation or approximately 1,000 times.	Acceptable, refer to changes.
	Additional Requirements 9. Certificate or Test Report that the product is	Acceptable, refer to changes.

Name of Bidder	Query/Comment	Response
	compliant and tested with the emission and immunity requirements of EN/IEC. Request to remove the said requirement as such compliance is already embedded with the ISO/IEC/PNS standards.	

The revised Technical Specifications Form and Checklist of Technical and Financial Documents are attached for prospective bidders' reference and use.

All other provisions of the bidding documents which are not affected shall remain in effect. For guidance and information of all concerned.

SGD
KENNETH G. RONQUILLO, MD, MPHM, CESO III
Undersecretary of Health
COBAC-E, Chairperson

Technical Specifications

Republic of the Philippines Department of Health TECHNICAL SPECIFICATIONS			
Item No. 1	**Glucometer**	Quantity / Unit	**2,000 pieces**
Name of Manufacturer:		Country of Origin:	
Brand:			
Total ABC: **PhP3,000,000.00**			
PURCHASER'S SPECIFICATION		**STATEMENT OF COMPLIANCE**	
A. Detailed Technical Specifications: 1. Test range: at least 19-600 mg/dL 2. Test Time: 5-10 seconds 3. Memory: at least 180 memory values/test results with date and time, automatically calculate the results, and with memory recall capability 4. Automatically calculate the results 5. Energy-saving device: Auto power off without any operation 6. Operation mode: Continuous operation 7. Test scenario settings/mode: can be marked before meal, after meal and control solution test 8. High definition, LCD digital display 9. Size: Manufacturer standards 10. Micro blood collection 11. Accurate measurement 12. Packing list: 12. a One (1) Blood Glucose Meter 12.b One (1) Blood Collection Device/ Lancing Device (must be conformity with MDD 93/42 EEC) 12.c One (1) carrying box/case 12.d 50 pcs. Test Strips 12.e 50 pcs. Lancets with protective cap 12.f With replaceable battery, can last up to 18 months operation **or approximately 1,000 times**			

B. <u>Additional requirements to be attached to Technical Specifications form arranged, numbered and tabbed as enumerated below:</u>

1. Valid and current Certificate of Medical Device Registration (CMDR) or Certificate of Medical Device Notification (CMDN) issued by Philippine Food and Drug Administration (PFDA) for lancet only;

2. Valid and current License to Operate (LTO) for Medical Device Importer/ Wholesaler issued by PFDA;

3. The bidder shall submit any of the following whichever is applicable:
   a) If the bidder is a manufacturer, certificate that the bidder manufactures the products/item;

Republic of the Philippines Department of Health TECHNICAL SPECIFICATIONS			
Item No. 1	**Glucometer**	Quantity / Unit	**2,000 pieces**
Name of Manufacturer:		Country of Origin:	
Brand:			
Total ABC: **PhP3,000,000.00**			
PURCHASER'S SPECIFICATION		**STATEMENT OF COMPLIANCE**	

or

b) If the bidder is an Exclusive/Authorized Distributor or Dealer of the products/items, Certificate or Contract from the manufacturer must be provided as proof that the bidder is an Exclusive/Authorized Distributor or Dealer of the products/items; or

c) If the bidder is an agent of the exclusive distributor or dealer, the following must be provided:
   i. Certificate or Distributor/Dealership Agreement by the Manufacturer with the distributor or dealer; and
   ii. Certificate or Contract/Dealership Agreement between the distributor/dealer and the bidder.

4. Valid and current Declaration of Conformity with appropriate ISO/IEC/PNS Standard issued to the manufacturer by an ISO certifying body or any appropriate agency or body;

5. 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 2nd page of Section VII. Technical Specifications of the Bidding Documents;

6. Warranty Certificate for at least one (1) year warranty on parts and services;

7. Certificate of availability of test strips in the local market;

8. Certificate that the product brand must be at least three (3) years in the local market;

9. Sworn Statement using the prescribed form.

C. <u>Upon delivery the following shall be complied with:</u>

1. Shelf life for test strips and lancet:

Must be fresh commercial stock with a total shelf life of twenty-four (24) months from the date of manufacture but not less than eighteen (18) months from the date of delivery

2. Packaging instructions:

a) Standard packaging of the manufacturer as approved by PFDA.

3. Labeling instructions:

a) On each unit and box, the following shall be imprinted or stickered with non-removable or permanent sticker or label that is binding and with residue and tearing if removed:

Philippine Government Property – Department of Health
NOT FOR SALE

D. <u>Additional Requirement to be submitted by the Lowest/Single Calculated Bidder (S/LCB):</u>

1. Submit one (1) sample during post-qualification and to be returned thereafter.

Republic of the Philippines Department of Health TECHNICAL SPECIFICATIONS			
Item No. 1	**Glucometer**	Quantity / Unit	**2,000 pieces**
Name of Manufacturer:		Country of Origin:	
Brand:			
Total ABC: **PhP3,000,000.00**			
PURCHASER'S SPECIFICATION		**STATEMENT OF COMPLIANCE**	

E. <u>Product Recall & Disposal:</u>

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;

_____
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

Legal Documents

☐ (a) Valid PhilGEPS Registration Certificate (Platinum Membership) (all pages) in accordance with Section 8.5.2 of the 2016 Revised IRR of RA No. 9184;

Technical Documents

☐ (b) Statement of the prospective bidder of all 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; **and**

☐ (c) Statement of the bidder's Single Largest Completed Contract (SLCC) similar to the contract to be bid *equivalent to at least twenty five percent (25%) of the ABC*, except under conditions provided for in Sections 23.4.1.3 and 23.4.2.4 of the 2016 Revised IRR of RA No. 9184, within the relevant period as provided in the Bidding Documents; **and**

☐ (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 after- sales/parts, if applicable; **and**

☐ (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.

Financial Documents

☐ (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" Document

☐ (h) If applicable, a duly signed joint venture agreement (JVA) in case the joint venture is already in existence;

or

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**

☐ (b) Original of duly signed and accomplished Price Schedule(s).

III. ADDITIONAL DOCUMENTARY REQUIREMENTS TO BE ATTACHED IN THE TECHINICAL SPECIFICATIONS FORM:

☐ (a) Valid and current Certificate of Medical Device Registration (CMDR) or Certificate of Medical Device Notification (CMDN) issued by Philippine Food and Drug Administration (PFDA) for lancet only;

☐ (b) Valid and current License to Operate (LTO) for Medical Device Importer/Wholesaler issued by PFDA;

☐ (c) The bidder shall submit any of the following whichever is applicable:

a) If the bidder is a manufacturer, certificate that the bidder manufactures the products/item; or

b) If the bidder is an Exclusive/Authorized Distributor or Dealer of the products/items, Certificate or Contract from the manufacturer must be provided as proof that the bidder is an Exclusive/Authorized Distributor or Dealer of the products/items; or

c) If the bidder is an agent of the exclusive distributor or dealer, the following must be provided:
   i. Certificate or Distributor/Dealership Agreement by the Manufacturer with the distributor or dealer; and
   ii. Certificate or Contract/Dealership Agreement between the distributor/dealer and the bidder.

☐ (d) Valid and current Declaration of Conformity with appropriate ISO/IEC/PNS Standard issued to the manufacturer by an ISO certifying body or any appropriate agency or body;

☐ (e) 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 2nd page of Section VII. Technical Specifications of the Bidding Documents;

☐ (f) Warranty Certificate for at least one (1) year warranty on parts and services;

☐ (g) Certificate that the product brand must be at least three (3) years in the local market;

☐ (h) Certificate of availability of test strips in the local market;

☐ (i) Sworn Statement using the prescribed form.

Note:

1) Please refer to https://doh.gov.ph/sites/default/files/basic-page/COBAC-Sample-Forms.pdf for the following requirements:

   a) Sworn Statement;
   b) Computation of NFCC;
   c) Manufacturer's Authorization;
   d) Authorization from the Main Distributor of the Manufacturer
   e) Secretary's Certificate;
   f) Special Power of Attorney;
   g) Statement of Ongoing Contracts; and
   h) Statement of SLCC.

2) For the following requirements, please refer to **GPPB Resolution No. 16-2020:**

   a) Bid Form;
   b) Price Schedule;
   c) Bid Securing Declaration; and
   d) Omnibus Sworn Statement