

**ANNEXURE-A**

**BMSIC/MEDICAL DEVICES/CONSUMABLE/19-04**

**Clarification in the light of queries/suggestions received from various firms during and after Pre-Bid Meeting held on 17/10/2019**

| S.N.     | Name of the Firm                                        | Bidders Queries                                                                                                                                                                                                                                                                                   | Present Clause                                                                                                                                                                                                                                                                                                                                                | Clarification/Amendment                                                                                                                                      |
|----------|---------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>1</b> | <b>M/s Roche Diabetes Care India Pvt. Ltd.</b>          | We are the direct Importer of Our Products from Original Equipment Manufacturer in Mannheim (Germany). We need to get the Annexure- IX (Manufacturer Authorization Form) from there. Thus requesting you to omit point no- 3 & 4 in Annexure- IX since its a global document.                     | Annexure-IX Manufacturer's Authorization Form                                                                                                                                                                                                                                                                                                                 | No change<br>In view of the fact that BMSICL needs to have a guarantee from the OEM in order to ensure uninterrupted Health Care Services.                   |
|          |                                                         | We are having Auto disable Lancet in the packing of 200pc/Box. It will of great help if you can allow us to quote the same packing in financial Bid.                                                                                                                                              | Annexure- I (Tender Product List)<br>NIT SI No. 3) Auto Disable Lancets 110 Nos/ pack                                                                                                                                                                                                                                                                         | <b>Annexure 1 (Tender Product List) Auto Disable Lancets- 100 Nos/ pack</b>                                                                                  |
| <b>2</b> | <b>M/s Sensa Core Medical Instrumentation Pvt. Ltd.</b> | With ref. to point no. 2.b (page no. 5 of 35) of the tender document, we wish to know whether the referred clause is a Mandatory? We repeat the clause:<br><b>"The bidders should quote the rates for the Glucometer Machine, Glucose Test Strips and Auto disable lancets in GENERIC NAMES".</b> | <b>Clause 2(b)</b> The Tender has been called in the generic names of Glucometer machine, Glucose test strips and Auto disable lancets. The bidders should quote the rates for the Glucometer machine, Glucose test strips and Auto disable lancets in generic names. The products offered shall comply with the tender specifications given in Annexure-VII. | No change<br><b>(The generic name must be labelled over the pack)</b>                                                                                        |
|          |                                                         | <b>Glucometer should work on "Code Free/ No Coding" basis as Coding base meters have become out-dated in the market.</b>                                                                                                                                                                          | ANNEXURE-III<br>List of the Item Quoted:- HSN CODE                                                                                                                                                                                                                                                                                                            | No change<br>(It shall be in accordance with guidelines issued by Government of India/ State Govt. from time to time)                                        |
|          |                                                         | With regard to previous experience, please add a clause for 60% to 70% of the required quantity of BMSICL. This will give assurance to BMSICL that the participant/ shortlisted party can supply material without any hindrance.                                                                  | <b>Clause 3 (f)-</b> Bidders shall submit self-attested copies of their manufacturing license (for manufacturer)/ import License (for direct importer)/ manufacturing & import license (for manufacturer as well as direct importer), invoices raised against the executed supply order/ orders of the quoted items in support of above mentioned conditions. | No change                                                                                                                                                    |
|          |                                                         | Product should be CE and USFDA for the better quality products.                                                                                                                                                                                                                                   | <b>Clause 3 ( h)</b> The Glucometer machine must have valid CE certificate as per Invitro Diagnostic Devices (IVD) or US FDA certificate or BIS Certificate and should be certified by the National Institutes of Biological (NIB), Govt. of India.                                                                                                           | <b>Clause 3 ( h) The Glucometer machine must have valid CE certificate as per Invitro Diagnostic Devices (IVD) or US FDA certificate or BIS Certificate.</b> |

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| 3 | M/s SD Biosensor Healthcare Pvt. Ltd. | Only Strip is certified by NIB, Govt. of India and not Device (Glucometer) which is need to be corrected. It is not regulated, it will regulated in jan 2020.                                                             | <b>Clause 3 ( h)</b> The Glucometer machine must have valid CE certificate as per Invitro Diagnostic Devices (IVD) or US FDA certificate or BIS Certificate and should be certified by the National Institutes of Biological (NIB), Govt. of India.                                                                                                                                                                                                    | <b>Clause 3 ( h)</b> The Glucometer machine must have valid CE certificate as per Invitro Diagnostic Devices (IVD) or US FDA certificate or BIS Certificate.                                                                                                                                                                                |
|   |                                       | Only few companies have Strip Ejection facility, which will lead to less competition.                                                                                                                                     | <b>Annexure VII Point no.12-</b> Device should Should have strip ejection button facility to avoid cross contamination to the operator.                                                                                                                                                                                                                                                                                                                | <b>Annexure VII Point no.12 i.e., Device should Should have strip ejection button facility to avoid cross contamination to the operator is ommitted</b>                                                                                                                                                                                     |
|   |                                       | Glucose Dehydrogenase Biosensor - Minimise Risk of Interference. No reactivity to any sugars other than glucose. More stable material in electrochemical reaction.<br>Assay Method- Not Mentioned                         | Clause 13- Demonstration of Technical Specifications & Performance: a) Before opening of the Price Bid, if it is decided by the Tender Inviting Authority to have a demonstration of the floated Medical devices for assessing the compliance to the technical specification as indicated in Section VII, then the bidder shall arrange for demonstration of offered items (of the same make & model as offered in the bid) at BMSICL at its own cost. | <b>During Demonstration the specificity &amp; sensitivity will be evaluated by the team of experts nominated by BMSICL.</b>                                                                                                                                                                                                                 |
|   |                                       | 0% to 70% - Lead to more accuracy<br>Haematocrit Range- Not Mentioned                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                             |
|   |                                       | Gold Electrode for accuracy and precision - As Gold is the most stable material in electrochemical reaction, Gold conducts electricity better than carbon, Gold has the advantage of corrosion resistance.                |                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                             |
|   |                                       | Pack Size of Auto Disable Lancets need to be Change to 100 (Page No. 25) Annexure I                                                                                                                                       | Annexure- I (Tender Product List)<br>NIT SI No. 3) Auto Disable Lancets 110 Nos/ pack                                                                                                                                                                                                                                                                                                                                                                  | <b>Annexure 1 (Tender Product List) Auto Disable Lancets- 100 Nos/ pack</b>                                                                                                                                                                                                                                                                 |
|   |                                       | Need to clear how many warehouse or how many location for the delivery.<br><br>Please clear the total number of consignee for the delivery of the products. Centralised or decentralised.<br>Delivery Location- Consignee | Clause 2(c) Rates should be quoted for each Glucometer machine, Glucose test strips and Auto disable lancets “on door delivery basis” in the format given in price bid. Conditional bid shall not be accepted. The delivery point shall be the different warehouses of BMSICL across the state of Bihar.                                                                                                                                               | <b>The warehouse details are mentioned on BMSICL webportal i.e.,www.bmsicl.gov.in. The Number of warehouses may be increased as per the requirement of BMSICL.</b>                                                                                                                                                                          |
| 4 |                                       | —                                                                                                                                                                                                                         | Annexure 1 Note 1) The device and test strips (per batch/packet) shall be quoted with 2 years of replacement warranty deliverable at the user site.                                                                                                                                                                                                                                                                                                    | Annexure 1 Note 1) The device and test strips (per batch/packet) shall be quoted with 2 years of replacement warranty deliverable at the user site. <b>The successful bidder has to replace the defective machine within a week of reporting.</b>                                                                                           |
| 5 |                                       | —                                                                                                                                                                                                                         | Clause 4(c) The rate quoted shall be per unit i.e. price per ml inclusive of all taxes (except GST) & duties including insurance, freight, handling charges at various heads etc. applicable at the time of bidding. It is clarified that in case of any change in the tax/duty rates the same may apply from time to time.                                                                                                                            | Clause 4(c) The rate quoted shall be per unit <b>as mentioned in annexure B</b> inclusive of all taxes (except GST) & duties including insurance, freight, handling charges at various heads etc. applicable at the time of bidding. It is clarified that in case of any change in the tax/duty rates the same may apply from time to time. |