



health

Department:

Health

REPUBLIC OF SOUTH AFRICA

NDoH-35(2023/2024)

**SUPPLY AND DELIVERY OF POINT OF CARE TESTING
DEVICES, SOFTWARE AND RELATED CONSUMABLES TO
THE DEPARTMENT OF HEALTH FOR NON-COMMUNICABLE
DISEASES AND PRIMARY HEALTH CARE FOR A PERIOD OF
THREE YEARS**

BID VALIDITY PERIOD: 120 DAYS

DATE ISSUED: 19 JANUARY 2024

CLOSING DATE AND TIME OF THE BID:

14 FEBRUARY 2024 AT 11H00AM

NON- COMPULSORY VIRTUAL BRIEFING SESSION:

31 JANUARY 2024 AT 10:00AM

Register in advance for this webinar:

https://zoom.us/webinar/register/WN_t6t5KnnRw2DaB6In-JmIA

PART A INVITATION TO BID

YOU ARE HEREBY INVITED TO BID FOR REQUIREMENTS OF THE NATIONAL DEPARTMENT OF HEALTH (NDOH)							
BID NUMBER:		NDoH-35(2023/2024)		CLOSING DATE:		14 FEBRUARY 2024	
				CLOSING TIME:		11:00	
DESCRIPTION		SUPPLY AND DELIVERY OF POINT OF CARE TESTING DEVICES, SOFTWARE AND RELATED CONSUMABLES TO THE DEPARTMENT OF HEALTH FOR NON- CONSUMABLE DISEASES AND PRIMARY HEALTH CARE FOR A PERIOD OF THREE (03) YEARS.					
BID RESPONSE DOCUMENTS MAY BE DEPOSITED IN THE BID BOX SITUATED AT (STREET ADDRESS)							
NATIONAL DEPARTMENT OF HEALTH							
1112 VOORTREKKER ROAD							
DR AB XUMA BUILDING (PREVIOUSLY EXXARO BUILDING) IN THABA TSHWANE							
PRETORIA							
BIDDING PROCEDURE ENQUIRIES MAY BE DIRECTED TO				TECHNICAL ENQUIRIES MAY BE DIRECTED TO:			
CONTACT PERSON				CONTACT PERSON			
TELEPHONE NUMBER				TELEPHONE NUMBER			
FACSIMILE NUMBER				FACSIMILE NUMBER			
E-MAIL ADDRESS		tenders@health.gov.za		E-MAIL ADDRESS		tenders@health.gov.za	
SUPPLIER INFORMATION							
NAME OF BIDDER							
POSTAL ADDRESS							
STREET ADDRESS							
TELEPHONE NUMBER		CODE		NUMBER			
CELLPHONE NUMBER							
FACSIMILE NUMBER		CODE		NUMBER			
E-MAIL ADDRESS							
VAT REGISTRATION NUMBER							
SUPPLIER COMPLIANCE STATUS		TAX COMPLIANCE SYSTEM PIN:		OR	CENTRAL SUPPLIER DATABASE No:	MAAA	
B-BBEE STATUS LEVEL VERIFICATION CERTIFICATE		TICK APPLICABLE BOX] <input type="checkbox"/> Yes <input type="checkbox"/> No		B-BBEE STATUS LEVEL SWORN AFFIDAVIT		[TICK APPLICABLE BOX] <input type="checkbox"/> Yes <input type="checkbox"/> No	
[A B-BBEE STATUS LEVEL VERIFICATION CERTIFICATE/ SWORN AFFIDAVIT (FOR EMES & QSEs) MUST BE SUBMITTED IN ORDER TO QUALIFY FOR PREFERENCE POINTS FOR B-BBEE]							
ARE YOU THE ACCREDITED REPRESENTATIVE IN SOUTH AFRICA FOR THE GOODS /SERVICES /WORKS OFFERED?		<input type="checkbox"/> Yes <input type="checkbox"/> No [IF YES ENCLOSE PROOF]		ARE YOU A FOREIGN BASED SUPPLIER FOR THE GOODS /SERVICES /WORKS OFFERED?		<input type="checkbox"/> Yes <input type="checkbox"/> No [IF YES, ANSWER THE QUESTIONNAIRE BELOW]	
QUESTIONNAIRE TO BIDDING FOREIGN SUPPLIERS							
IS THE ENTITY A RESIDENT OF THE REPUBLIC OF SOUTH AFRICA (RSA)?						<input type="checkbox"/> YES <input type="checkbox"/> NO	
DOES THE ENTITY HAVE A BRANCH IN THE RSA?						<input type="checkbox"/> YES <input type="checkbox"/> NO	
DOES THE ENTITY HAVE A PERMANENT ESTABLISHMENT IN THE RSA?						<input type="checkbox"/> YES <input type="checkbox"/> NO	
DOES THE ENTITY HAVE ANY SOURCE OF INCOME IN THE RSA?						<input type="checkbox"/> YES <input type="checkbox"/> NO	
IS THE ENTITY LIABLE IN THE RSA FOR ANY FORM OF TAXATION?						<input type="checkbox"/> YES <input type="checkbox"/> NO	
IF THE ANSWER IS "NO" TO ALL OF THE ABOVE, THEN IT IS NOT A REQUIREMENT TO REGISTER FOR A TAX COMPLIANCE STATUS SYSTEM PIN CODE FROM THE SOUTH AFRICAN REVENUE SERVICE (SARS) AND IF NOT REGISTER AS PER 2.3 BELOW.							

PART B TERMS AND CONDITIONS FOR BIDDING

<p>1. BID SUBMISSION:</p> <p>1.1. BIDS MUST BE DELIVERED BY THE STIPULATED TIME TO THE CORRECT ADDRESS. LATE BIDS WILL NOT BE ACCEPTED FOR CONSIDERATION.</p> <p>1.2. ALL BIDS MUST BE SUBMITTED ON THE OFFICIAL FORMS PROVIDED–(NOT TO BE RE-TYPED) OR IN THE MANNER PRESCRIBED IN THE BID DOCUMENT.</p> <p>1.3. THIS BID IS SUBJECT TO THE PREFERENTIAL PROCUREMENT POLICY FRAMEWORK ACT, 2000 AND THE PREFERENTIAL PROCUREMENT REGULATIONS, 2017, THE GENERAL CONDITIONS OF CONTRACT (GCC) AND, IF APPLICABLE, ANY OTHER SPECIAL CONDITIONS OF CONTRACT.</p> <p>1.4. THE SUCCESSFUL BIDDER WILL BE REQUIRED TO FILL IN AND SIGN A WRITTEN CONTRACT FORM (SBD7).</p>	<p>2. TAX COMPLIANCE REQUIREMENTS</p> <p>2.1 BIDDERS MUST ENSURE COMPLIANCE WITH THEIR TAX OBLIGATIONS.</p> <p>2.2 BIDDERS ARE REQUIRED TO SUBMIT THEIR UNIQUE PERSONAL IDENTIFICATION NUMBER (PIN) ISSUED BY SARS TO ENABLE THE ORGAN OF STATE TO VERIFY THE TAXPAYER'S PROFILE AND TAX STATUS.</p> <p>2.3 APPLICATION FOR TAX COMPLIANCE STATUS (TCS) PIN MAY BE MADE VIA E-FILING THROUGH THE SARS WEBSITE WWW.SARS.GOV.ZA.</p> <p>2.4 BIDDERS MAY ALSO SUBMIT A PRINTED TCS CERTIFICATE TOGETHER WITH THE BID.</p> <p>2.5 IN BIDS WHERE CONSORTIA / JOINT VENTURES / SUB-CONTRACTORS ARE INVOLVED, EACH PARTY MUST SUBMIT A SEPARATE TCS CERTIFICATE / PIN / CSD NUMBER.</p> <p>2.6 WHERE NO TCS PIN IS AVAILABLE BUT THE BIDDER IS REGISTERED ON THE CENTRAL SUPPLIER DATABASE (CSD), A CSD NUMBER MUST BE PROVIDED.</p> <p>2.7 NO BIDS WILL BE CONSIDERED FROM PERSONS IN THE SERVICE OF THE STATE, COMPANIES WITH DIRECTORS WHO ARE PERSONS IN THE SERVICE OF THE STATE, OR CLOSE CORPORATIONS WITH MEMBERS PERSONS IN THE SERVICE OF THE STATE."</p>
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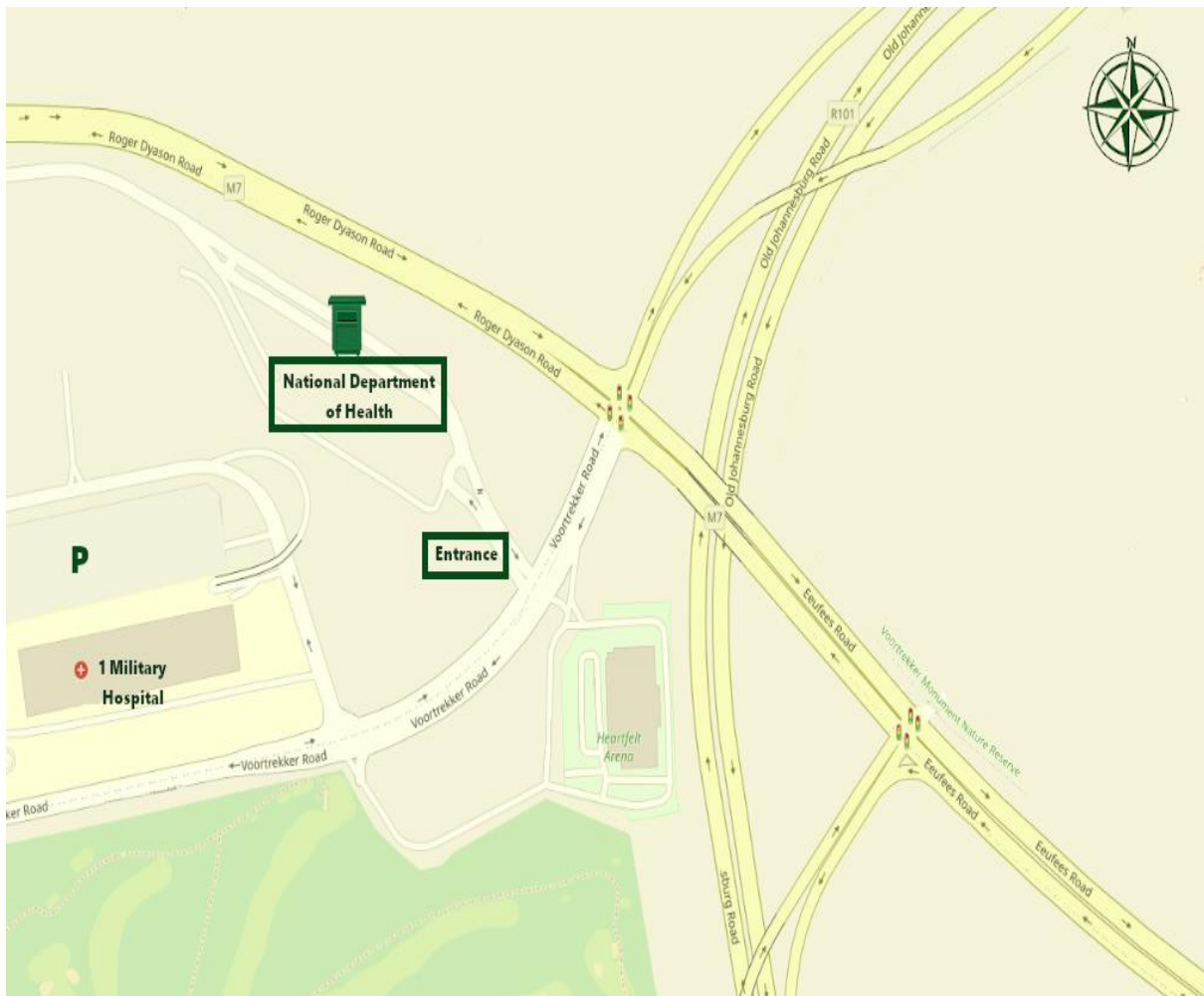
NB: FAILURE TO PROVIDE / OR COMPLY WITH ANY OF THE ABOVE PARTICULARS MAY RENDER THE BID INVALID.

SIGNATURE OF BIDDER:

CAPACITY UNDER WHICH THIS BID IS SIGNED:

(NB: Proof of authority must be submitted e.g. company resolution)

DATE:



THE NATIONAL TREASURY

Republic of South Africa



GOVERNMENT PROCUREMENT: GENERAL CONDITIONS OF CONTRACT

July 2010

GOVERNMENT PROCUREMENT
GENERAL CONDITIONS OF CONTRACT
July 2010

NOTES

The purpose of this document is to:

- (i) Draw special attention to certain general conditions applicable to government bids, contracts and orders; and
- (ii) To ensure that clients be familiar with regard to the rights and obligations of all parties involved in doing business with government.

In this document words in the singular also mean in the plural and vice versa and words in the masculine also mean in the feminine and neuter.

- The General Conditions of Contract will form part of all bid documents and may not be amended.
- Special Conditions of Contract (SCC) relevant to a specific bid, should be compiled separately for every bid (if applicable) and will supplement the General Conditions of Contract. Whenever there is a conflict, the provisions in the SCC shall prevail.

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General Conditions of Contract

1. Definitions

1. The following terms shall be interpreted as indicated:
 - 1.1 “Closing time” means the date and hour specified in the bidding documents for the receipt of bids.
 - 1.2 “Contract” means the written agreement entered into between the purchaser and the supplier, as recorded in the contract form signed by the parties, including all attachments and appendices thereto and all documents incorporated by reference therein.
 - 1.3 “Contract price” means the price payable to the supplier under the contract for the full and proper performance of his contractual obligations.
 - 1.4 “Corrupt practice” means the offering, giving, receiving, or soliciting of any thing of value to influence the action of a public official in the procurement process or in contract execution.
 - 1.5 "Countervailing duties" are imposed in cases where an enterprise abroad is subsidized by its government and encouraged to market its products internationally.
 - 1.6 “Country of origin” means the place where the goods were mined, grown or produced or from which the services are supplied. Goods are produced when, through manufacturing, processing or substantial and major assembly of components, a commercially recognized new product results that is substantially different in basic characteristics or in purpose or utility from its components.
 - 1.7 “Day” means calendar day.
 - 1.8 “Delivery” means delivery in compliance of the conditions of the contract or order.
 - 1.9 “Delivery ex stock” means immediate delivery directly from stock actually on hand.
 - 1.10 “Delivery into consignees store or to his site” means delivered and unloaded in the specified store or depot or on the specified site in compliance with the conditions of the contract or order, the supplier bearing all risks and charges involved until the supplies are so delivered and a valid receipt is obtained.
 - 1.11 "Dumping" occurs when a private enterprise abroad market its goods on own initiative in the RSA at lower prices than that of the country of origin and which have the potential to harm the local industries in the

RSA.

- 1.12 "Force majeure" means an event beyond the control of the supplier and not involving the supplier's fault or negligence and not foreseeable. Such events may include, but is not restricted to, acts of the purchaser in its sovereign capacity, wars or revolutions, fires, floods, epidemics, quarantine restrictions and freight embargoes.
- 1.13 "Fraudulent practice" means a misrepresentation of facts in order to influence a procurement process or the execution of a contract to the detriment of any bidder, and includes collusive practice among bidders (prior to or after bid submission) designed to establish bid prices at artificial non-competitive levels and to deprive the bidder of the benefits of free and open competition.
- 1.14 "GCC" means the General Conditions of Contract.
- 1.15 "Goods" means all of the equipment, machinery, and/or other materials that the supplier is required to supply to the purchaser under the contract.
- 1.16 "Imported content" means that portion of the bidding price represented by the cost of components, parts or materials which have been or are still to be imported (whether by the supplier or his subcontractors) and which costs are inclusive of the costs abroad, plus freight and other direct importation costs such as landing costs, dock dues, import duty, sales duty or other similar tax or duty at the South African place of entry as well as transportation and handling charges to the factory in the Republic where the supplies covered by the bid will be manufactured.
- 1.17 "Local content" means that portion of the bidding price which is not included in the imported content provided that local manufacture does take place.
- 1.18 "Manufacture" means the production of products in a factory using labour, materials, components and machinery and includes other related value-adding activities.
- 1.19 "Order" means an official written order issued for the supply of goods or works or the rendering of a service.
- 1.20 "Project site," where applicable, means the place indicated in bidding documents.
- 1.21 "Purchaser" means the organization purchasing the goods.
- 1.22 "Republic" means the Republic of South Africa.
- 1.23 "SCC" means the Special Conditions of Contract.
- 1.24 "Services" means those functional services ancillary to the supply of the goods, such as transportation and any other incidental services, such as installation, commissioning, provision of technical assistance, training, catering, gardening, security, maintenance and other such

obligations of the supplier covered under the contract.

- 1.25 “Written” or “in writing” means handwritten in ink or any form of electronic or mechanical writing.

2. Application

- 2.1 These general conditions are applicable to all bids, contracts and orders including bids for functional and professional services, sales, hiring, letting and the granting or acquiring of rights, but excluding immovable property, unless otherwise indicated in the bidding documents.
- 2.2 Where applicable, special conditions of contract are also laid down to cover specific supplies, services or works.
- 2.3 Where such special conditions of contract are in conflict with these general conditions, the special conditions shall apply.

3. General

- 3.1 Unless otherwise indicated in the bidding documents, the purchaser shall not be liable for any expense incurred in the preparation and submission of a bid. Where applicable a non-refundable fee for documents may be charged.
- 3.2 With certain exceptions, invitations to bid are only published in the Government Tender Bulletin. The Government Tender Bulletin may be obtained directly from the Government Printer, Private Bag X85, Pretoria 0001, or accessed electronically from www.treasury.gov.za

4. Standards

- 4.1 The goods supplied shall conform to the standards mentioned in the bidding documents and specifications.

5. Use of contract documents and information; inspection.

- 5.1 The supplier shall not, without the purchaser’s prior written consent, disclose the contract, or any provision thereof, or any specification, plan, drawing, pattern, sample, or information furnished by or on behalf of the purchaser in connection therewith, to any person other than a person employed by the supplier in the performance of the contract. Disclosure to any such employed person shall be made in confidence and shall extend only so far as may be necessary for purposes of such performance.
- 5.2 The supplier shall not, without the purchaser’s prior written consent, make use of any document or information mentioned in GCC clause 5.1 except for purposes of performing the contract.
- 5.3 Any document, other than the contract itself mentioned in GCC clause 5.1 shall remain the property of the purchaser and shall be returned (all copies) to the purchaser on completion of the supplier’s performance under the contract if so required by the purchaser.
- 5.4 The supplier shall permit the purchaser to inspect the supplier’s records relating to the performance of the supplier and to have them audited by auditors appointed by the purchaser, if so required by the purchaser.

6. Patent rights

- 6.1 The supplier shall indemnify the purchaser against all third-party claims of infringement of patent, trademark, or industrial design rights arising from use of the goods or any part thereof by the purchaser.

7. Performance security

- 7.1 Within thirty (30) days of receipt of the notification of contract award, the successful bidder shall furnish to the purchaser the performance security of the amount specified in SCC.
- 7.2 The proceeds of the performance security shall be payable to the purchaser as compensation for any loss resulting from the supplier's failure to complete his obligations under the contract.
- 7.3 The performance security shall be denominated in the currency of the contract, or in a freely convertible currency acceptable to the purchaser and shall be in one of the following forms:
- (a) a bank guarantee or an irrevocable letter of credit issued by a reputable bank located in the purchaser's country or abroad, acceptable to the purchaser, in the form provided in the bidding documents or another form acceptable to the purchaser; or
 - (b) a cashier's or certified cheque
- 7.4 The performance security will be discharged by the purchaser and returned to the supplier not later than thirty (30) days following the date of completion of the supplier's performance obligations under the contract, including any warranty obligations, unless otherwise specified in SCC.

8. Inspections, tests and analyses

- 8.1 All pre-bidding testing will be for the account of the bidder.
- 8.2 If it is a bid condition that supplies to be produced or services to be rendered should at any stage during production or execution or on completion be subject to inspection, the premises of the bidder or contractor shall be open, at all reasonable hours, for inspection by a representative of the Department or an organization acting on behalf of the Department.
- 8.3 If there are no inspection requirements indicated in the bidding documents and no mention is made in the contract, but during the contract period it is decided that inspections shall be carried out, the purchaser shall itself make the necessary arrangements, including payment arrangements with the testing authority concerned.
- 8.4 If the inspections, tests and analyses referred to in clauses 8.2 and 8.3 show the supplies to be in accordance with the contract requirements, the cost of the inspections, tests and analyses shall be defrayed by the purchaser.
- 8.5 Where the supplies or services referred to in clauses 8.2 and 8.3 do not comply with the contract requirements, irrespective of whether such supplies or services are accepted or not, the cost in connection with these inspections, tests or analyses shall be defrayed by the supplier.
- 8.6 Supplies and services which are referred to in clauses 8.2 and 8.3 and which do not comply with the contract requirements may be rejected.
- 8.7 Any contract supplies may on or after delivery be inspected, tested or

analyzed and may be rejected if found not to comply with the requirements of the contract. Such rejected supplies shall be held at the cost and risk of the supplier who shall, when called upon, remove them immediately at his own cost and forthwith substitute them with supplies which do comply with the requirements of the contract. Failing such removal the rejected supplies shall be returned at the suppliers cost and risk. Should the supplier fail to provide the substitute supplies forthwith, the purchaser may, without giving the supplier further opportunity to substitute the rejected supplies, purchase such supplies as may be necessary at the expense of the supplier.

- 8.8 The provisions of clauses 8.4 to 8.7 shall not prejudice the right of the purchaser to cancel the contract on account of a breach of the conditions thereof, or to act in terms of Clause 23 of GCC.

9. Packing

- 9.1 The supplier shall provide such packing of the goods as is required to prevent their damage or deterioration during transit to their final destination, as indicated in the contract. The packing shall be sufficient to withstand, without limitation, rough handling during transit and exposure to extreme temperatures, salt and precipitation during transit, and open storage. Packing, case size and weights shall take into consideration, where appropriate, the remoteness of the goods' final destination and the absence of heavy handling facilities at all points in transit.
- 9.2 The packing, marking, and documentation within and outside the packages shall comply strictly with such special requirements as shall be expressly provided for in the contract, including additional requirements, if any, specified in SCC, and in any subsequent instructions ordered by the purchaser.

10. Delivery and documents

- 10.1 Delivery of the goods shall be made by the supplier in accordance with the terms specified in the contract. The details of shipping and/or other documents to be furnished by the supplier are specified in SCC.
- 10.2 Documents to be submitted by the supplier are specified in SCC.

11. Insurance

- 11.1 The goods supplied under the contract shall be fully insured in a freely convertible currency against loss or damage incidental to manufacture or acquisition, transportation, storage and delivery in the manner specified in the SCC.

12. Transportation

- 12.1 Should a price other than an all-inclusive delivered price be required, this shall be specified in the SCC.

13. Incidental services

- 13.1 The supplier may be required to provide any or all of the following services, including additional services, if any, specified in SCC:
- (a) performance or supervision of on-site assembly and/or commissioning of the supplied goods;
 - (b) furnishing of tools required for assembly and/or maintenance of the supplied goods;
 - (c) furnishing of a detailed operations and maintenance manual for each appropriate unit of the supplied goods;

- (d) performance or supervision or maintenance and/or repair of the supplied goods, for a period of time agreed by the parties, provided that this service shall not relieve the supplier of any warranty obligations under this contract; and
- (e) training of the purchaser's personnel, at the supplier's plant and/or on-site, in assembly, start-up, operation, maintenance, and/or repair of the supplied goods.

13.2 Prices charged by the supplier for incidental services, if not included in the contract price for the goods, shall be agreed upon in advance by the parties and shall not exceed the prevailing rates charged to other parties by the supplier for similar services.

14. Spare parts

14.1 As specified in SCC, the supplier may be required to provide any or all of the following materials, notifications, and information pertaining to spare parts manufactured or distributed by the supplier:

- (a) such spare parts as the purchaser may elect to purchase from the supplier, provided that this election shall not relieve the supplier of any warranty obligations under the contract; and
- (b) in the event of termination of production of the spare parts:
 - (i) Advance notification to the purchaser of the pending termination, in sufficient time to permit the purchaser to procure needed requirements; and
 - (ii) following such termination, furnishing at no cost to the purchaser, the blueprints, drawings, and specifications of the spare parts, if requested.

15. Warranty

15.1 The supplier warrants that the goods supplied under the contract are new, unused, of the most recent or current models, and that they incorporate all recent improvements in design and materials unless provided otherwise in the contract. The supplier further warrants that all goods supplied under this contract shall have no defect, arising from design, materials, or workmanship (except when the design and/or material is required by the purchaser's specifications) or from any act or omission of the supplier, that may develop under normal use of the supplied goods in the conditions prevailing in the country of final destination.

15.2 This warranty shall remain valid for twelve (12) months after the goods, or any portion thereof as the case may be, have been delivered to and accepted at the final destination indicated in the contract, or for eighteen (18) months after the date of shipment from the port or place of loading in the source country, whichever period concludes earlier, unless specified otherwise in SCC.

15.3 The purchaser shall promptly notify the supplier in writing of any claims arising under this warranty.

15.4 Upon receipt of such notice, the supplier shall, within the period specified in SCC and with all reasonable speed, repair or replace the defective goods or parts thereof, without costs to the purchaser.

15.5 If the supplier, having been notified, fails to remedy the defect(s) within the period specified in SCC, the purchaser may proceed to take

such remedial action as may be necessary, at the supplier's risk and expense and without prejudice to any other rights which the purchaser may have against the supplier under the contract.

16. Payment

- 16.1 The method and conditions of payment to be made to the supplier under this contract shall be specified in SCC.
- 16.2 The supplier shall furnish the purchaser with an invoice accompanied by a copy of the delivery note and upon fulfillment of other obligations stipulated in the contract.
- 16.3 Payments shall be made promptly by the purchaser, but in no case later than thirty (30) days after submission of an invoice or claim by the supplier.
- 16.4 Payment will be made in Rand unless otherwise stipulated in SCC.

17. Prices

- 17.1 Prices charged by the supplier for goods delivered and services performed under the contract shall not vary from the prices quoted by the supplier in his bid, with the exception of any price adjustments authorized in SCC or in the purchaser's request for bid validity extension, as the case may be.

18. Contract amendments

- 18.1 No variation in or modification of the terms of the contract shall be made except by written amendment signed by the parties concerned.

19. Assignment

- 19.1 The supplier shall not assign, in whole or in part, its obligations to perform under the contract, except with the purchaser's prior written consent.

20. Subcontracts

- 20.1 The supplier shall notify the purchaser in writing of all subcontracts awarded under this contracts if not already specified in the bid. Such notification, in the original bid or later, shall not relieve the supplier from any liability or obligation under the contract.

21. Delays in the supplier's performance

- 21.1 Delivery of the goods and performance of services shall be made by the supplier in accordance with the time schedule prescribed by the purchaser in the contract.
- 21.2 If at any time during performance of the contract, the supplier or its subcontractor(s) should encounter conditions impeding timely delivery of the goods and performance of services, the supplier shall promptly notify the purchaser in writing of the fact of the delay, its likely duration and its cause(s). As soon as practicable after receipt of the supplier's notice, the purchaser shall evaluate the situation and may at his discretion extend the supplier's time for performance, with or without the imposition of penalties, in which case the extension shall be ratified by the parties by amendment of contract.
- 21.3 No provision in a contract shall be deemed to prohibit the obtaining of supplies or services from a national department, provincial department, or a local authority.
- 21.4 The right is reserved to procure outside of the contract small quantities or to have minor essential services executed if an emergency arises, the

supplier's point of supply is not situated at or near the place where the supplies are required, or the supplier's services are not readily available.

21.5 Except as provided under GCC Clause 25, a delay by the supplier in the performance of its delivery obligations shall render the supplier liable to the imposition of penalties, pursuant to GCC Clause 22, unless an extension of time is agreed upon pursuant to GCC Clause 21.2 without the application of penalties.

21.6 Upon any delay beyond the delivery period in the case of a supplies contract, the purchaser shall, without canceling the contract, be entitled to purchase supplies of a similar quality and up to the same quantity in substitution of the goods not supplied in conformity with the contract and to return any goods delivered later at the supplier's expense and risk, or to cancel the contract and buy such goods as may be required to complete the contract and without prejudice to his other rights, be entitled to claim damages from the supplier.

22. Penalties

22.1 Subject to GCC Clause 25, if the supplier fails to deliver any or all of the goods or to perform the services within the period(s) specified in the contract, the purchaser shall, without prejudice to its other remedies under the contract, deduct from the contract price, as a penalty, a sum calculated on the delivered price of the delayed goods or unperformed services using the current prime interest rate calculated for each day of the delay until actual delivery or performance. The purchaser may also consider termination of the contract pursuant to GCC Clause 23.

23. Termination for default

23.1 The purchaser, without prejudice to any other remedy for breach of contract, by written notice of default sent to the supplier, may terminate this contract in whole or in part:

- (a) if the supplier fails to deliver any or all of the goods within the period(s) specified in the contract, or within any extension thereof granted by the purchaser pursuant to GCC Clause 21.2;
- (b) if the Supplier fails to perform any other obligation(s) under the contract; or
- (c) if the supplier, in the judgment of the purchaser, has engaged in corrupt or fraudulent practices in competing for or in executing the contract.

23.2 In the event the purchaser terminates the contract in whole or in part, the purchaser may procure, upon such terms and in such manner as it deems appropriate, goods, works or services similar to those undelivered, and the supplier shall be liable to the purchaser for any excess costs for such similar goods, works or services. However, the supplier shall continue performance of the contract to the extent not terminated.

23.3 Where the purchaser terminates the contract in whole or in part, the purchaser may decide to impose a restriction penalty on the supplier by prohibiting such supplier from doing business with the public sector for a period not exceeding 10 years.

23.4 If a purchaser intends imposing a restriction on a supplier or any

person associated with the supplier, the supplier will be allowed a time period of not more than fourteen (14) days to provide reasons why the envisaged restriction should not be imposed. Should the supplier fail to respond within the stipulated fourteen (14) days the purchaser may regard the intended penalty as not objected against and may impose it on the supplier.

23.5 Any restriction imposed on any person by the Accounting Officer / Authority will, at the discretion of the Accounting Officer / Authority, also be applicable to any other enterprise or any partner, manager, director or other person who wholly or partly exercises or exercised or may exercise control over the enterprise of the first-mentioned person, and with which enterprise or person the first-mentioned person, is or was in the opinion of the Accounting Officer / Authority actively associated.

23.6 If a restriction is imposed, the purchaser must, within five (5) working days of such imposition, furnish the National Treasury, with the following information:

- (i) the name and address of the supplier and / or person restricted by the purchaser;
- (ii) the date of commencement of the restriction
- (iii) the period of restriction; and
- (iv) the reasons for the restriction.

These details will be loaded in the National Treasury's central database of suppliers or persons prohibited from doing business with the public sector.

23.7 If a court of law convicts a person of an offence as contemplated in sections 12 or 13 of the Prevention and Combating of Corrupt Activities Act, No. 12 of 2004, the court may also rule that such person's name be endorsed on the Register for Tender Defaulters. When a person's name has been endorsed on the Register, the person will be prohibited from doing business with the public sector for a period not less than five years and not more than 10 years. The National Treasury is empowered to determine the period of restriction and each case will be dealt with on its own merits. According to section 32 of the Act the Register must be open to the public. The Register can be perused on the National Treasury website.

24. Anti-dumping and countervailing duties and rights

24.1 When, after the date of bid, provisional payments are required, or anti-dumping or countervailing duties are imposed, or the amount of a provisional payment or anti-dumping or countervailing right is increased in respect of any dumped or subsidized import, the State is not liable for any amount so required or imposed, or for the amount of any such increase. When, after the said date, such a provisional payment is no longer required or any such anti-dumping or countervailing right is abolished, or where the amount of such provisional payment or any such right is reduced, any such favourable difference shall on demand be paid forthwith by the contractor to the State or the State may deduct such amounts from moneys (if any) which may otherwise be due to the contractor in regard to supplies or services which he delivered or rendered, or is to deliver or render in terms of the contract or any other contract or any other amount which

may be due to him

25. Force Majeure

- 25.1 Notwithstanding the provisions of GCC Clauses 22 and 23, the supplier shall not be liable for forfeiture of its performance security, damages, or termination for default if and to the extent that his delay in performance or other failure to perform his obligations under the contract is the result of an event of force majeure.
- 25.2 If a force majeure situation arises, the supplier shall promptly notify the purchaser in writing of such condition and the cause thereof. Unless otherwise directed by the purchaser in writing, the supplier shall continue to perform its obligations under the contract as far as is reasonably practical, and shall seek all reasonable alternative means for performance not prevented by the force majeure event.

26. Termination for insolvency

- 26.1 The purchaser may at any time terminate the contract by giving written notice to the supplier if the supplier becomes bankrupt or otherwise insolvent. In this event, termination will be without compensation to the supplier, provided that such termination will not prejudice or affect any right of action or remedy which has accrued or will accrue thereafter to the purchaser.

27. Settlement of Disputes

- 27.1 If any dispute or difference of any kind whatsoever arises between the purchaser and the supplier in connection with or arising out of the contract, the parties shall make every effort to resolve amicably such dispute or difference by mutual consultation.
- 27.2 If, after thirty (30) days, the parties have failed to resolve their dispute or difference by such mutual consultation, then either the purchaser or the supplier may give notice to the other party of his intention to commence with mediation. No mediation in respect of this matter may be commenced unless such notice is given to the other party.
- 27.3 Should it not be possible to settle a dispute by means of mediation, it may be settled in a South African court of law.
- 27.4 Mediation proceedings shall be conducted in accordance with the rules of procedure specified in the SCC.
- 27.5 Notwithstanding any reference to mediation and/or court proceedings herein,
- (a) the parties shall continue to perform their respective obligations under the contract unless they otherwise agree; and
 - (b) the purchaser shall pay the supplier any monies due the supplier.

28. Limitation of liability

- 28.1 Except in cases of criminal negligence or willful misconduct, and in the case of infringement pursuant to Clause 6;
- (a) the supplier shall not be liable to the purchaser, whether in contract, tort, or otherwise, for any indirect or consequential loss or damage, loss of use, loss of production, or loss of profits or interest costs, provided that this exclusion shall not apply to any obligation of the supplier to pay penalties and/or damages to the purchaser; and

	(b) the aggregate liability of the supplier to the purchaser, whether under the contract, in tort or otherwise, shall not exceed the total contract price, provided that this limitation shall not apply to the cost of repairing or replacing defective equipment.
29. Governing language	29.1 The contract shall be written in English. All correspondence and other documents pertaining to the contract that is exchanged by the parties shall also be written in English.
30. Applicable law	30.1 The contract shall be interpreted in accordance with South African laws, unless otherwise specified in SCC.
31. Notices	<p>31.1 Every written acceptance of a bid shall be posted to the supplier concerned by registered or certified mail and any other notice to him shall be posted by ordinary mail to the address furnished in his bid or to the address notified later by him in writing and such posting shall be deemed to be proper service of such notice</p> <p>31.2 The time mentioned in the contract documents for performing any act after such aforesaid notice has been given, shall be reckoned from the date of posting of such notice.</p>
32. Taxes and duties	<p>32.1 A foreign supplier shall be entirely responsible for all taxes, stamp duties, license fees, and other such levies imposed outside the purchaser's country.</p> <p>32.2 A local supplier shall be entirely responsible for all taxes, duties, license fees, etc., incurred until delivery of the contracted goods to the purchaser.</p> <p>32.3 No contract shall be concluded with any bidder whose tax matters are not in order. Prior to the award of a bid the Department must be in possession of a tax clearance certificate, submitted by the bidder. This certificate must be an original issued by the South African Revenue Services.</p>
33. National Industrial Participation Programme (NIP)	33.1 The NIP Programme administered by the Department of Trade and Industry shall be applicable to all contracts that are subject to the NIP obligation.
34 Prohibition of Restrictive practices	<p>34.1 In terms of section 4 (1) (b) (iii) of the Competition Act No. 89 of 1998, as amended, an agreement between, or concerted practice by, firms, or a decision by an association of firms, is prohibited if it is between parties in a horizontal relationship and if a bidder (s) is / are or a contractor(s) was / were involved in collusive bidding (or bid rigging).</p> <p>34.2 If a bidder(s) or contractor(s), based on reasonable grounds or evidence obtained by the purchaser, has / have engaged in the restrictive practice referred to above, the purchaser may refer the matter to the Competition Commission for investigation and possible imposition of administrative penalties as contemplated in the Competition Act No. 89 of 1998.</p>

- 34.3 If a bidder(s) or contractor(s), has / have been found guilty by the Competition Commission of the restrictive practice referred to above, the purchaser may, in addition and without prejudice to any other remedy provided for, invalidate the bid(s) for such item(s) offered, and / or terminate the contract in whole or part, and / or restrict the bidder(s) or contractor(s) from conducting business with the public sector for a period not exceeding ten (10) years and / or claim damages from the bidder(s) or contractor(s) concerned.

Js General Conditions of Contract (revised July 2010)

AUTHORITY TO SIGN THE STANDARD BIDDING DOCUMENTS (SBD) ON BEHALF OF AN ENTITY.

“Only authorized signatories may sign the original and all copies of the bid where required.

In the case of a **ONE-PERSON CONCERN** submitting a bid, this shall be clearly stated.

In case of a **COMPANY** submitting a bid, include a copy of a **resolution by its board of directors** authorizing a director or other official of the company to sign the documents on behalf of the company.

In the case of a **CLOSED CORPORATION** submitting a bid, include a copy of a **resolution by its members** authorizing a member or other official of the corporation to sign the documents on each member's behalf.

In the case of a **PARTNERSHIP** submitting a bid, **all the partners shall** sign the documents, unless one partner or a group of partners has been authorized to sign on behalf of each partner, in which case **proof of such authorization** shall be included in the bid.

In the case of a **JOINT VENTURE** submitting a bid, include **a resolution** of each company of the Joint Venture together with a resolution by its members authorizing a member of the Joint Venture to sign the documents on behalf of the Joint Venture.”

Accept that failure to submit proof of Authorization to sign the bid may result in the bid being declared non-responsive.

AUTHORITY OF SIGNATORY

Signatories for companies, closed corporations and partnerships must establish their authority **BY ATTACHING TO THIS FORM, ON THEIR ORGANISATIONS'S LETTERHEAD STATIONERY**, a copy of the relevant resolution by their Board of Directors, Members or Partners, duly signed and dated.

An **EXAMPLE** is shown below for a COMPANY:

ZETHMBE TRADERS (Pty) Ltd	
By resolution of the Board of Directors taken on <i>01 AUGUST 2000</i> ,	
MR M BONAKELE	
has been duly authorised to sign all documents in connection with	
Contract no NDoH-01/2023/2024, and any contract which may arise	
there from, on behalf of <i>Mabel House (Pty) Ltd.</i>	
SIGNED ON BEHALF OF THE COMPANY:	(Signature of Managing Director)
IN HIS CAPACITY AS:	Managing Director
DATE:	<i>01 AUGUST 2000</i>
SIGNATURE OF SIGNATORY:	(Signature of <i>M Bonakele</i>)
As witnesses:	
1.
2.
Signature of person authorised to sign the bid:	
Date:	

PRICING SCHEDULE – FIRM PRICES (PURCHASES)

NOTE: ONLY FIRM PRICES WILL BE ACCEPTED. NON-FIRM PRICES (INCLUDING PRICES SUBJECT TO RATES OF EXCHANGE VARIATIONS) WILL NOT BE CONSIDERED

IN CASES WHERE DIFFERENT DELIVERY POINTS INFLUENCE THE PRICING, A SEPARATE PRICING SCHEDULE MUST BE SUBMITTED FOR EACH DELIVERY POINT

Name of bidder.....	Bid number: NDoH 35/2023-2024
Closing Time 11:00AM	Closing date: 14 FEBRUARY 2024

OFFER TO BE VALID FOR **120** DAYS FROM THE CLOSING DATE OF BID.

ITEM NO.	QUANTITY	DESCRIPTION	BID PRICE IN RSA CURRENCY ** (ALL APPLICABLE TAXES INCLUDED)
----------	----------	-------------	-----------------------------------------------------------------

-
- Required by:
 - At:
.....
 - Brand and model
 - Country of origin
 - Does the offer comply with the specification(s)? *YES/NO
 - If not to specification, indicate deviation(s)
 - Period required for delivery
*Delivery: Firm/not firm
 - Delivery basis

Note: All delivery costs must be included in the bid price, for delivery at the prescribed destination.

** "all applicable taxes" includes value- added tax, pay as you earn, income tax, unemployment insurance fund contributions and skills development levies.

*Delete if not applicable

BIDDER'S DISCLOSURE

1. PURPOSE OF THE FORM

Any person (natural or juristic) may make an offer or offers in terms of this invitation to bid. In line with the principles of transparency, accountability, impartiality, and ethics as enshrined in the Constitution of the Republic of South Africa and further expressed in various pieces of legislation, it is required for the bidder to make this declaration in respect of the details required hereunder.

Where a person/s are listed in the Register for Tender Defaulters and / or the List of Restricted Suppliers, that person will automatically be disqualified from the bid process.

2. Bidder's declaration

- 2.1 Is the bidder, or any of its directors / trustees / shareholders / members / partners or any person having a controlling interest¹ in the enterprise, employed by the state? **YES/NO**

- 2.1.1 If so, furnish particulars of the names, individual identity numbers, and, if applicable, state employee numbers of sole proprietor/ directors / trustees / shareholders / members/ partners or any person having a controlling interest in the enterprise, in table below.

Full Name	Identity Number	Name of State institution

- 2.2 Do you, or any person connected with the bidder, have a relationship

¹ the power, by one person or a group of persons holding the majority of the equity of an enterprise, alternatively, the person/s having the deciding vote or power to influence or to direct the course and decisions of the enterprise.

with any person who is employed by the procuring institution? **YES/NO**

2.2.1 If so, furnish particulars:

.....
.....

2.3 Does the bidder or any of its directors / trustees / shareholders / members / partners or any person having a controlling interest in the enterprise have any interest in any other related enterprise whether or not they are bidding for this contract? **YES/NO**

2.3.1 If so, furnish particulars:

.....
.....

3 DECLARATION

I, _____ the _____ undersigned,
(name)..... in
submitting the accompanying bid, do hereby make the following
statements that I certify to be true and complete in every respect:

- 3.1 I have read and I understand the contents of this disclosure;
- 3.2 I understand that the accompanying bid will be disqualified if this disclosure is found not to be true and complete in every respect;
- 3.3 The bidder has arrived at the accompanying bid independently from, and without consultation, communication, agreement or arrangement with any competitor. However, communication between partners in a joint venture or consortium² will not be construed as collusive bidding.
- 3.4 In addition, there have been no consultations, communications, agreements or arrangements with any competitor regarding the quality, quantity, specifications, prices, including methods, factors or formulas used to calculate prices, market allocation, the intention or decision to submit or not to submit the bid, bidding with the intention not to win the bid and conditions or delivery particulars of the products or services to which this bid invitation relates.
- 3.4 The terms of the accompanying bid have not been, and will not be, disclosed by the bidder, directly or indirectly, to any competitor, prior to the date and time of the official bid opening or of the awarding of the contract.
- 3.5 There have been no consultations, communications, agreements or arrangements made by the bidder with any official of the procuring

² Joint venture or Consortium means an association of persons for the purpose of combining their expertise, property, capital, efforts, skill and knowledge in an activity for the execution of a contract.

institution in relation to this procurement process prior to and during the bidding process except to provide clarification on the bid submitted where so required by the institution; and the bidder was not involved in the drafting of the specifications or terms of reference for this bid.

- 3.6 I am aware that, in addition and without prejudice to any other remedy provided to combat any restrictive practices related to bids and contracts, bids that are suspicious will be reported to the Competition Commission for investigation and possible imposition of administrative penalties in terms of section 59 of the Competition Act No 89 of 1998 and or may be reported to the National Prosecuting Authority (NPA) for criminal investigation and or may be restricted from conducting business with the public sector for a period not exceeding ten (10) years in terms of the Prevention and Combating of Corrupt Activities Act No 12 of 2004 or any other applicable legislation.

I CERTIFY THAT THE INFORMATION FURNISHED IN PARAGRAPHS 1, 2 and 3 ABOVE IS CORRECT.

I ACCEPT THAT THE STATE MAY REJECT THE BID OR ACT AGAINST ME IN TERMS OF PARAGRAPH 6 OF PFMA SCM INSTRUCTION 03 OF 2021/22 ON PREVENTING AND COMBATING ABUSE IN THE SUPPLY CHAIN MANAGEMENT SYSTEM SHOULD THIS DECLARATION PROVE TO BE FALSE.

.....
Signature	Date
.....
Position	Name of bidder

This document must be signed and submitted together with your bid

THE NATIONAL INDUSTRIAL PARTICIPATION PROGRAMME

INTRODUCTION

The National Industrial Participation (NIP) Programme, which is applicable to all government procurement contracts that have an imported content, became effective on the 1 September 1996. The NIP policy and guidelines were fully endorsed by Cabinet on 30 April 1997. In terms of the Cabinet decision, all state and parastatal purchases / lease contracts (for goods, works and services) entered into after this date, are subject to the NIP requirements. NIP is obligatory and therefore must be complied with. The Industrial Participation Secretariat (IPS) of the Department of Trade and Industry (DTI) is charged with the responsibility of administering the programme.

1 PILLARS OF THE PROGRAMME

- 1.1 The NIP obligation is benchmarked on the imported content of the contract. Any contract having an imported content equal to or exceeding US\$ 10 million or other currency equivalent to US\$ 10 million will have a NIP obligation. This threshold of US\$ 10 million can be reached as follows:
 - (a) Any single contract with imported content exceeding US\$10 million.
or
 - (b) Multiple contracts for the same goods, works or services each with imported content exceeding US\$3 million awarded to one seller over a 2 year period which in total exceeds US\$10 million.
or
 - (c) A contract with a renewable option clause, where should the option be exercised the total value of the imported content will exceed US\$10 million.
or
 - (d) Multiple suppliers of the same goods, works or services under the same contract, where the value of the imported content of each allocation is equal to or exceeds US\$ 3 million worth of goods, works or services to the same government institution, which in total over a two (2) year period exceeds US\$10 million.
- 1.2 The NIP obligation applicable to suppliers in respect of sub-paragraphs 1.1 (a) to 1.1 (c) above will amount to 30 % of the imported content whilst suppliers in respect of paragraph 1.1 (d) shall incur 30% of the total NIP obligation on a *pro-rata* basis.
- 1.3 To satisfy the NIP obligation, the DTI would negotiate and conclude agreements such as investments, joint ventures, sub-contracting, licensee production, export promotion, sourcing arrangements and research and development (R&D) with partners or suppliers.

- 1.4 A period of seven years has been identified as the time frame within which to discharge the obligation.

2 REQUIREMENTS OF THE DEPARTMENT OF TRADE AND INDUSTRY

- 2.1 In order to ensure effective implementation of the programme, successful bidders (contractors) are required to, immediately after the award of a contract that is in excess of **R10 million** (ten million Rands), submit details of such a contract to the DTI for reporting purposes.

- 2.2 The purpose for reporting details of contracts in excess of the amount of R10 million (ten million Rands) is to cater for multiple contracts for the same goods, works or services; renewable contracts and multiple suppliers for the same goods, works or services under the same contract as provided for in paragraphs 1.1.(b) to 1.1. (d) above.

3 BID SUBMISSION AND CONTRACT REPORTING REQUIREMENTS OF BIDDERS AND SUCCESSFUL BIDDERS (CONTRACTORS)

- 3.1 Bidders are required to sign and submit this Standard Bidding Document (SBD 5) together with the bid on the closing date and time.

- 3.2 In order to accommodate multiple contracts for the same goods, works or services; renewable contracts and multiple suppliers for the same goods, works or services under the same contract as indicated in sub-paragraphs 1.1 (b) to 1.1 (d) above and to enable the DTI in determining the NIP obligation, successful bidders (contractors) are required, immediately after being officially notified about any successful bid with a value in excess of R10 million (ten million Rands), to contact and furnish the DTI with the following information:

- Bid / contract number.
- Description of the goods, works or services.
- Date on which the contract was accepted.
- Name, address and contact details of the government institution.
- Value of the contract.
- Imported content of the contract, if possible.

- 3.3 The information required in paragraph 3.2 above must be sent to the Department of Trade and Industry, Private Bag X 84, Pretoria, 0001 for the attention of Mr Elias Malapane within five (5) working days after award of the contract. Mr Malapane may be contacted on telephone (012) 394 1401, facsimile (012) 394 2401 or e-mail at Elias@thedti.gov.za for further details about the programme.

4 PROCESS TO SATISFY THE NIP OBLIGATION

- 4.1 Once the successful bidder (contractor) has made contact with and furnished the DTI with the information required, the following steps will be followed:
- a. the contractor and the DTI will determine the NIP obligation;
 - b. the contractor and the DTI will sign the NIP obligation agreement;

- c. the contractor will submit a performance guarantee to the DTI;
- d. the contractor will submit a business concept for consideration and approval by the DTI;
- e. upon approval of the business concept by the DTI, the contractor will submit detailed business plans outlining the business concepts;
- f. the contractor will implement the business plans; and
- g. the contractor will submit bi-annual progress reports on approved plans to the DTI.

4.2 The NIP obligation agreement is between the DTI and the successful bidder (contractor) and, therefore, does not involve the purchasing institution.

Bid number **NDoH-35(2023/2024)**

14 FEBRUARY 2024 @ 11:00AM

Name of bidder.....

Postal address

.....

Signature..... Name (in print).....

Date.....

Js475wc

PREFERENCE POINTS CLAIM FORM IN TERMS OF THE PREFERENTIAL PROCUREMENT REGULATIONS 2022

This preference form must form part of all tenders invited. It contains general information and serves as a claim form for preference points for specific goals.

NB: BEFORE COMPLETING THIS FORM, TENDERERS MUST STUDY THE GENERAL CONDITIONS, DEFINITIONS AND DIRECTIVES APPLICABLE IN RESPECT OF THE TENDER AND PREFERENTIAL PROCUREMENT REGULATIONS, 2022

1. GENERAL CONDITIONS

1.1 The following preference point systems are applicable to invitations to tender:

- the 80/20 system for requirements with a Rand value of up to R50 000 000 (all applicable taxes included); and
- the 90/10 system for requirements with a Rand value above R50 000 000 (all applicable taxes included).

1.2 **To be completed by the organ of state**

(delete whichever is not applicable for this tender).

- a) The applicable preference point system for this tender is the 90/10 preference point system.
- b) The applicable preference point system for this tender is the 80/20 preference point system.
- c) Either the **90/10 or 80/20 preference point system** will be applicable in this tender. The lowest/ highest acceptable tender will be used to determine the accurate system once tenders are received.

1.3 Points for this tender (even in the case of a tender for income-generating contracts) shall be awarded for:

- (a) Price; and
- (b) Specific Goals.

1.4 **To be completed by the organ of state:**

The maximum points for this tender are allocated as follows:

	POINTS
PRICE	90
SPECIFIC GOALS	10
Total points for Price and SPECIFIC GOALS	100

1.5 Failure on the part of a tenderer to submit proof or documentation required in terms of

this tender to claim points for specific goals with the tender, will be interpreted to mean that preference points for specific goals are not claimed.

- 1.6 The organ of state reserves the right to require of a tenderer, either before a tender is adjudicated or at any time subsequently, to substantiate any claim in regard to preferences, in any manner required by the organ of state.
- 1.7 The company must submit ID copies of Directors and or shareholders with their bid document or quotation to substantiate points claimed. The share certificate reflecting the number of shares held by each member or director of the company to qualify for the points claimed must be submitted. In case of a claiming points for disability the company must submit a registered Doctor noted or document as evidence of the disability.

2. DEFINITIONS

- (a) **“tender”** means a written offer in the form determined by an organ of state in response to an invitation to provide goods or services through price quotations, competitive tendering process or any other method envisaged in legislation;
- (b) **“price”** means an amount of money tendered for goods or services, and includes all applicable taxes less all unconditional discounts;
- (c) **“rand value”** means the total estimated value of a contract in Rand, calculated at the time of bid invitation, and includes all applicable taxes;
- (d) **“tender for income-generating contracts”** means a written offer in the form determined by an organ of state in response to an invitation for the origination of income-generating contracts through any method envisaged in legislation that will result in a legal agreement between the organ of state and a third party that produces revenue for the organ of state, and includes, but is not limited to, leasing and disposal of assets and concession contracts, excluding direct sales and disposal of assets through public auctions; and
- (e) **“the Act”** means the Preferential Procurement Policy Framework Act, 2000 (Act No. 5 of 2000).

3. FORMULAE FOR PROCUREMENT OF GOODS AND SERVICES

3.1. POINTS AWARDED FOR PRICE

3.1.1 THE 80/20 OR 90/10 PREFERENCE POINT SYSTEMS

A maximum of 80 or 90 points is allocated for price on the following basis:

$$\begin{array}{ccc}
 \mathbf{80/20} & \mathbf{or} & \mathbf{90/10} \\
 \\
 \mathbf{Ps} = \mathbf{80} \left(\mathbf{1} - \frac{\mathbf{Pt} - \mathbf{Pmin}}{\mathbf{Pmin}} \right) & \mathbf{or} & \mathbf{Ps} = \mathbf{90} \left(\mathbf{1} - \frac{\mathbf{Pt} - \mathbf{Pmin}}{\mathbf{Pmin}} \right)
 \end{array}$$

Where

Ps = Points scored for price of tender under consideration

Pt = Price of tender under consideration

Pmin = Price of lowest acceptable tender

3.2. FORMULAE FOR DISPOSAL OR LEASING OF STATE ASSETS AND INCOME GENERATING PROCUREMENT

3.2.1. POINTS AWARDED FOR PRICE

A maximum of 80 or 90 points is allocated for price on the following basis:

$$\begin{array}{ccc} \mathbf{80/20} & \mathbf{or} & \mathbf{90/10} \\ \mathbf{Ps = 80 \left(1 + \frac{Pt - P_{max}}{P_{max}} \right)} & \mathbf{or} & \mathbf{Ps = 90 \left(1 + \frac{Pt - P_{max}}{P_{max}} \right)} \end{array}$$

Where

- Ps = Points scored for price of tender under consideration
Pt = Price of tender under consideration
Pmax = Price of highest acceptable tender

4. POINTS AWARDED FOR SPECIFIC GOALS

- 4.1. In terms of Regulation 4(2); 5(2); 6(2) and 7(2) of the Preferential Procurement Regulations, preference points must be awarded for specific goals stated in the tender. For the purposes of this tender the tenderer will be allocated points based on the goals stated in table 1 below as may be supported by proof/ documentation stated in the conditions of this tender:
- 4.2. In cases where organs of state intend to use Regulation 3(2) of the Regulations, which states that, if it is unclear whether the 80/20 or 90/10 preference point system applies, an organ of state must, in the tender documents, stipulate in the case of—
- (a) an invitation for tender for income-generating contracts, that either the 80/20 or 90/10 preference point system will apply and that the highest acceptable tender will be used to determine the applicable preference point system; or
 - (b) any other invitation for tender, that either the 80/20 or 90/10 preference point system will apply and that the lowest acceptable tender will be used to determine the applicable preference point system,
- then the organ of state must indicate the points allocated for specific goals for both the 90/10 and 80/20 preference point system.

Table 1: Specific goals for the tender and points claimed are indicated per the table below.

(Note to organs of state: Where either the 90/10 or 80/20 preference point system is applicable, corresponding points must also be indicated as such.

Note to tenderers: The tenderer must indicate how they claim points for each preference point system.)

The specific goals allocated points in terms of this tender	Number of points allocated (90/10 system) (To be completed by the organ of state)	Percentage ownership equity (To be completed by the tenderer)	Number of points claimed (90/10 system) (To be completed by the tenderer)
HDI	4		
Women	2		
People with Disabilities	2		
Promotion of South African owned enterprises	2		

DECLARATION WITH REGARD TO COMPANY/FIRM

4.3. Name of company/firm.....

4.4. Company registration number:

4.5. TYPE OF COMPANY/ FIRM

- ☐ Partnership/Joint Venture / Consortium
- ☐ One-person business/sole propriety
- ☐ Close corporation
- ☐ Public Company
- ☐ Personal Liability Company
- ☐ (Pty) Limited
- ☐ Non-Profit Company
- ☐ State Owned Company

[TICK APPLICABLE BOX]

4.6. I, the undersigned, who is duly authorised to do so on behalf of the company/firm, certify that the points claimed, based on the specific goals as advised in the tender, qualifies the company/ firm for the preference(s) shown and I acknowledge that:

- i) The information furnished is true and correct;
- ii) The preference points claimed are in accordance with the General Conditions as indicated in paragraph 1 of this form;
- iii) In the event of a contract being awarded as a result of points claimed as shown

in paragraphs 1.4 and 4.2, the contractor may be required to furnish documentary proof to the satisfaction of the organ of state that the claims are correct;

iv) If the specific goals have been claimed or obtained on a fraudulent basis or any of the conditions of contract have not been fulfilled, the organ of state may, in addition to any other remedy it may have –

- (a) disqualify the person from the tendering process;
- (b) recover costs, losses or damages it has incurred or suffered as a result of that person's conduct;
- (c) cancel the contract and claim any damages which it has suffered as a result of having to make less favourable arrangements due to such cancellation;
- (d) recommend that the tenderer or contractor, its shareholders and directors, or only the shareholders and directors who acted on a fraudulent basis, be restricted from obtaining business from any organ of state for a period not exceeding 10 years, after the *audi alteram partem* (hear the other side) rule has been applied; and
- (e) forward the matter for criminal prosecution, if deemed necessary.

.....
SIGNATURE(S) OF TENDERER(S)

SURNAME AND NAME:

DATE:

ADDRESS:

.....

.....

.....

TERMS OF REFERENCE AND THE SPECIAL CONDITIONS OF CONTRACT (SCC) FOR NDOH 35-2023/2024: SUPPLY AND DELIVERY OF POINT OF CARE TESTING DEVICES, SOFTWARE AND RELATED CONSUMABLES TO THE DEPARTMENT OF HEALTH FOR NON-COMMUNICABLE DISEASES AND PRIMARY HEALTH CARE FOR A PERIOD OF THREE YEARS

1. CONTRACT BRIEF

This bid is for the supply, delivery, and commissioning of the Point of Care Testing Medical Devices to all provinces. This is part of the implementation of the National Non-Communicable Disease Campaign (NCDc) by the Cluster: Non-Communicable Diseases across all provinces. The bid is inclusive of training on the use of the machines by the supplier/s to end-users/Community Health Workers (CHW) in various districts and related maintenance and repair work during the warranty period.

2. LEGISLATIVE FRAMEWORK

2.1 This bid and all contracts emanating there from will be subject to General Conditions of Contract (GCC) issued in accordance with Treasury Regulation 16A published in terms of the Public Finance Management Act, 1999 (Act 1 of 1999) as well as the Preferential Procurement Policy Framework Act 2000 (PPPFA) with its latest 2017 regulations.

2.2 The Special Conditions of Contract (SCC) are supplementary to that of General Conditions of Contract. However, where the Special Conditions of Contract are in conflict with the General Conditions of Contract, the Special Conditions of Contract prevail.

2.3 This bid is subject to all applicable industry related legislation, particularly the legislation stated below:

2.3.1 Medicines and Related Substances Amendment Act, No. 72 of 2008 (Amendment Act) read together with a further Amendment Act, Medicines and Related Substances Act No. 14 of 2015 and its Regulations and Guidelines;

2.3.2 Hazardous Substances Act No. 15 of 1973; and

2.3.3 Occupational Health and Safety Act No. 85 of 1993.

3. BRIEFING SESSION FOR BIDDERS

A non-compulsory briefing session for potential bidders shall be held as follows:

Date: 31 January 2024

Time: 10:00am

Online: Virtual

4. Key Functionality Requirements

4.1 **The logistics plan** that will indicate the bidder's operational plan (elements) for:

- 4.1.1 Supply and delivery processes and arrangements with customers
- 4.1.2 Lead time and process from receipt of purchase order
- 4.1.3 Detailed plan for supply and delivery for each province or district
- 4.1.4 Indicate the capacity to supply and deliver and provide an agreement from the OEM

4.2 **Technical competency** should reflect the following

- 4.2.1 Clinical application specialist(s) must have a profile that indicates training experience and qualifications which are medical field related
- 4.2.2 Technical personnel must have relevant tertiary qualification(s) and/or OEM trained certificate on Medical Equipment bidding for
- 4.2.3 Bidder(s) must detail the training that would be offered and indicate who will offer the required training within clearly defined time lines/schedules
- 4.2.4 References of the last 3 purchase orders in private or public sectors where a similar project/commissioning was completed. The project timelines of the submitted orders to be attached.

4.3 Bidders **profiles** should comprise the following:

- 4.3.1 Proof of physical address(es) or lease agreement(s) or municipal account(s).
- 4.3.2 Where there is an agreement with a third party, the third party together with contact details to be declared. Copy of third-party agreement signed by both parties with proof of location of the third party or parties
- 4.3.3 List of technical personnel with names, location, tertiary qualification (NQF Level)
- 4.3.4 Organogram of the technical division

5. COMPLIANCE

Bidder should as part of the bid response submit the following:

5.1 Detailed Technical Specifications (**Annexure A**) to verify compliance

5.2 South African Health Products Regulatory Authority (SAHPRA) Licence OR in the event that an approved medical device establishment license and/or registration certificate cannot be obtained from SAHPRA prior to the closing date and time of the bid, the bidder must submit evidence of application made to the Regulatory Authority, to be licensed as a medical device establishment (in the form of an Acknowledgement Letter received and payment (not old than three months) from the South African Health Products Regulatory Authority)

5.3 OEM original brochure for each item offered, the brochure must be in colour and clearly labelled with the item number of offer or operating manuals

5.4 The latest Quality Assurance Standards Certificates

5.4.1 ISO 9001:2008 from OEM / SANS 9001:2008 -Quality Management Systems from OEM

5.4.2 ISO 13485: 2004 / SANS 13485: 2003: Medical Devices - Quality Management Systems from OEM

5.4.3 ISO 15197:2013 or latest

5.5 Where applicable, Radiation Control License must be submitted with the bid at closing date and time for relevant items. The license must be registered under the bidder's name or a letter of authorization from the license holder where the license is not in the name of the bidder

5.6 Items offered must comply with an acceptable relevant international electrical safety standard such as IEC 601–1-2 for Medical Equipment and related safety against Electromagnetic interference. Proof of compliance/ certification from the OEM must be submitted at the closing date and time of bid

6. Branding

6.1 The item on offer must be clearly branded by the OEM including Name Plate (with serial number, date of manufacture, model, and Medical Equipment classification).

6.2 Medical Equipment on offer must have the make and model visible from the front.

6.3 Any offered Medical Equipment not meeting the above requirements may be automatically disqualified prior or post award.

7. Right of Award

The department reserves its following rights -

- 7.1 To award the bid in part or in full;
- 7.2 Not to make any award in this bid or accept any bids submitted;
- 7.3 Award the bid to more than one (1) bidder for the same item (multiple-award);
- 7.4 Request further technical information from any bidder after the closing date;
- 7.5 Request sample submission for physical and technical evaluation by the Evaluation Committee at a venue as determined by the committee.
- 7.6 Verify information and documentation of the bidder(s);
- 7.7 Not to accept any of the bids submitted;
- 7.8 To withdraw or amend any of the bid conditions by notice in writing to all bidders prior to closing of the bid and post award; and
- 7.9 In the event that an incorrect award has been made to remedy the matter in any lawful manner it may deem fit.
- 7.10 To negotiate price and conditions with any (Shortlisted) bidder

8. Multiple Award

- 8.1 The State reserves the right to award the same item (not the same brand model) to more than one (1) bidder to address item availability and compatibility. Due diligence will be applied to ensure that pricing is affordable, market related and aligned to end-user requirements.
- 8.2 The following shall be taken into consideration when contemplating a multiple award:
 - 8.2.1 Capacity to meet the expected demand according to the end-user requirements;
 - 8.2.2 Mitigation of risk if the item is unavailable; and
 - 8.2.3 The maximum number of suppliers per item to be awarded will be at the discretion of the BEC.

9. DELIVERY

The Equipment should be delivered fully functional with all the required accessories and where applicable, consumables such as batteries, required number of cuffs, hoses, strips, test solutions etc.

10. EVALUATION CRITERIA

This bid will be evaluated in three (03) Phases as indicated hereunder:

Phase 1: Testing compliance to the eligibility criteria (mandatory requirements) mentioned on the preceding paragraph. Bidders failing in this phase will be disqualified from the next evaluation phase

Phase 2: Bidders that have satisfied the mandatory requirements will be assessed against the technical (functionality) evaluation criteria as indicated below. The bidder must achieve a minimum of 70 points out of a possible 100 points to proceed to the next Phase of evaluation. Bids that fail to achieve the minimum required points will be disqualified and consequently not be considered for further evaluation; and

Phase 3: In this Phase bids will be evaluated on ninety **(90)** points for Price and Ten **(10)** points for Preference points system (HDI and RDP). The 90/10 preference points system will be applied.

It is the responsibility of each bidder to ensure that all applicable taxes are included in the offer. Bidders must ensure that they factor in VAT for offers above R1 million as it is a compulsory requirement of the VAT Administration Act. If an entity not registered as VAT vendor is awarded a bidder, it is expected to register for VAT within 21 days of being awarded a contract and produce such proof of registration to the departmental bid official/s

As a rule, the NDoH is not responsible for making a payment towards VAT on bidders that were awarded contracts without the inclusion thereof at the time of the bid closure.

11 MANDATORY REQUIREMENTS

NB: Failure to submit/attach proof of the following requirements with the bid leads to the disqualification of the bidder's proposal:

11.1 Compliance with all Tax Clearance requirements: Attach/ Tax Compliance Status Pin certificate, Central Supplier Database Number, where consortium/joint ventures/ sub-contractor are involved, each party to the association must submit separate Tax Clearance requirements.

11.2 A resolution authorising a particular person to sign the bid documents. The letter should be in the letterhead of the company where applicable and should be duly signed.

11.3 Product Knowledge and Understanding indicating a Solid demonstration of knowledge and understanding of products is required. Bidders are required to submit certificates demonstrating that the lead personnel have been trained (technical and or application specialist training) by the Original Equipment Manufacturer as indicated on the authorisation letter.

Functionality Evaluation Criteria Guideline

ANNEXURE

1.	Company Medical Equipment Experience	25
2.	Operational Strategy	30
3.	Capacity	30
4.	Risk Management Strategy	15

	Total	100
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NO	CRITERIA	CRITERIA	WEIGHT															
1	Company Medical Equipment Experience	<p>Bidders to provide a comprehensive illustration of the company experience in the medical equipment field in the private and or public sector that demonstrates working experience in relation to supply, delivery, installation, commissioning, training and maintenance, contract values and periods, physical address of premises, date of entry into the medical field, products marketed, list of customers that have bought the above products etc. Bidders are required to submit three contactable reference letters from their clients on client's letterhead.</p> <p>REFERENCE LETTERS WITH THE REQUIRED INFORMATION:</p> <table><tr><th>No</th><th>Description</th><th>Values</th></tr><tr><td>1.</td><td>3 or more reference letters that consist of all 5 elements required</td><td>3</td></tr><tr><td>2.</td><td>2 reference letters that consist of all 4 elements required</td><td>2</td></tr><tr><td>3.</td><td>One reference letter that consist of 3 and less elements required</td><td>1</td></tr><tr><td>4.</td><td>No reference letter / reference letters not providing information required</td><td>0</td></tr></table>	No	Description	Values	1.	3 or more reference letters that consist of all 5 elements required	3	2.	2 reference letters that consist of all 4 elements required	2	3.	One reference letter that consist of 3 and less elements required	1	4.	No reference letter / reference letters not providing information required	0	25
No	Description	Values																
1.	3 or more reference letters that consist of all 5 elements required	3																
2.	2 reference letters that consist of all 4 elements required	2																
3.	One reference letter that consist of 3 and less elements required	1																
4.	No reference letter / reference letters not providing information required	0																
2	Operation Strategy	<p>Bidders must include a full strategy demonstrating the ability to carry out the requirements of the bid in terms of supply and delivery, commissioning, training and maintenance, lead times, spares, and consumables. The bidder must also provide detailed plans for calibration, service, and repair for the equipment throughout the provinces.</p> <table><tr><th>No</th><th>Description</th><th>Values</th></tr><tr><td>1.</td><td>Response addresses and exceeds 6 elements as stated above</td><td>3</td></tr><tr><td>2.</td><td>Response addresses 5 elements as stated above</td><td>2</td></tr><tr><td>3.</td><td>Response addresses 4 elements as stated above</td><td>1</td></tr><tr><td>4.</td><td>Response address 3 and less elements as stated above</td><td>0</td></tr></table>	No	Description	Values	1.	Response addresses and exceeds 6 elements as stated above	3	2.	Response addresses 5 elements as stated above	2	3.	Response addresses 4 elements as stated above	1	4.	Response address 3 and less elements as stated above	0	30
No	Description	Values																
1.	Response addresses and exceeds 6 elements as stated above	3																
2.	Response addresses 5 elements as stated above	2																
3.	Response addresses 4 elements as stated above	1																
4.	Response address 3 and less elements as stated above	0																

NO	CRITERIA	CRITERIA	WEIGHT															
3	Capacity	<p>Bidders must demonstrate that they have the necessary capacity to undertake a national project of this nature in terms of human resources with requisite skills (submit profiles/ CVs of current technical personnel). Coverage and proof of geographical locations of workshop facilities is required (i.e. lease agreements and or municipal utility account) and or proof of arrangements with third parties for such.</p> <table><tr><th>No</th><th>Description</th><th>Value</th></tr><tr><td>1.</td><td>Coverage or geographical location in six (6) or more provinces</td><td>3</td></tr><tr><td>2.</td><td>Coverage or geographical location in four (4) to five (5) provinces</td><td>2</td></tr><tr><td>3.</td><td>Coverage or geographical location in two (2) to three (3) provinces</td><td>1</td></tr><tr><td>4.</td><td>Zero (0) – one (1) coverage or geographical location</td><td>0</td></tr></table>	No	Description	Value	1.	Coverage or geographical location in six (6) or more provinces	3	2.	Coverage or geographical location in four (4) to five (5) provinces	2	3.	Coverage or geographical location in two (2) to three (3) provinces	1	4.	Zero (0) – one (1) coverage or geographical location	0	30
No	Description	Value																
1.	Coverage or geographical location in six (6) or more provinces	3																
2.	Coverage or geographical location in four (4) to five (5) provinces	2																
3.	Coverage or geographical location in two (2) to three (3) provinces	1																
4.	Zero (0) – one (1) coverage or geographical location	0																
4	Risk Management	<p>Bidders must include a risk management strategy to mitigate against any supply risk and equipment uptime such as (equipment call outs, loan units' availability, stock availability, insurance etc.) that might arise within the duration of the supply period.</p> <table><tr><th>No</th><th>Description</th><th>Values</th></tr><tr><td>1.</td><td>Risk management strategy addresses and exceeds the requirements</td><td>3</td></tr><tr><td>2.</td><td>Risk management strategy addresses the requirements</td><td>2</td></tr><tr><td>3.</td><td>Risk management strategy partially addresses the requirements</td><td>1</td></tr><tr><td>4.</td><td>Risk management strategy does not address the requirements/ No risk management strategy</td><td>0</td></tr></table>	No	Description	Values	1.	Risk management strategy addresses and exceeds the requirements	3	2.	Risk management strategy addresses the requirements	2	3.	Risk management strategy partially addresses the requirements	1	4.	Risk management strategy does not address the requirements/ No risk management strategy	0	15
No	Description	Values																
1.	Risk management strategy addresses and exceeds the requirements	3																
2.	Risk management strategy addresses the requirements	2																
3.	Risk management strategy partially addresses the requirements	1																
4.	Risk management strategy does not address the requirements/ No risk management strategy	0																
		Total	100															
		Minimum Functionality threshold	70															

12 The score for functionality will be calculated as follows:

Each BEC member will rate each individual criterion on the score sheet using the following value scale:

Performance	Description	Score
Very Good	Response addresses and exceeds the functionality requirements	3
Compliant	Response addresses all functionality requirements	2
Requires Attention	Response partially addresses the functionality requirements	1
Inadequate	Response <u>did not address</u> the functionality requirements	0

The value scored for each criterion will be multiplied with the specified weighting for the relevant criterion to obtain the marks scored for each criterion. These marks will be added and expressed as a fraction of the best possible score for all criteria.

This score will be converted to a percentage and **only** bidders that have met or exceeded the minimum threshold of 70 for functionality will be considered for further evaluation.

13. PRICE AND HISTIRICALLY DISADVANTANGED INDIVIDUAL

13.1 POINTS AWARDED FOR SPECIFIC GOALS

In terms of Regulation 4(2); 5(2); 6(2) and 7(2) of the Preferential Procurement Regulations 2022, preference points must be awarded for specific goals stated in the tender. For the purposes of this tender the tenderer will be allocated points based on the goals stated in table 1 below as may be supported by proof/ documentation stated in the conditions of this tender:

In cases where organs of state intend to use Regulation 3(2) of the Regulations, which states that, if it is unclear whether the 80/20 or 90/10 preference point system applies, an organ of state must, in the tender documents, stipulate in the case of—

- (a) an invitation for tender for income-generating contracts, that either the 80/20 or 90/10 preference point system will apply and that the highest acceptable tender will be used to determine the applicable preference point system; or
- (b) any other invitation for tender, that either the 80/20 or 90/10 preference point system will apply and that the lowest acceptable tender will be used to determine the applicable preference point system, then the organ of state must indicate the points allocated for specific goals for both the 90/10 and 80/20 preference point system.

Table 1: Specific goals for the tender and points claimed are indicated per the table below.

(Note to organs of state: Where either the 90/10 or 80/20 preference point system is applicable, corresponding points must also be indicated as such.

Note to tenderers: The tenderer must indicate how they claim points for each preference point system.)

The specific goals allocated points in terms of this tender	Number of points allocated (90/10 system) (To be completed by the organ of state)	Percentage ownership equity (To be completed by the tenderer)	Number of points claimed (90/10 system) (To be completed by the tenderer)
HDI	4		
Women	2		
People with Disabilities	2		
Promotion of South African owned enterprises	2		

	Portable Upper Arm,Adult Blood Pressure Monitor, Electronic, NIBP	Complies Yes/No	Provide your answers /Comments in this Column. You are advised to be straight to the point.
1	Description		
	Portable Electronic Upperarm blood pressure measuring device for adults		
2	Product Offered:		
2.1	Make:		
2.2	Model:		
2.3	Initial Manufacturing year of Model:		
3	Technical Specification		
3.1	The unit must measure blood pressure non-invasively.		
3.2	Self test procedure at switch-on		
3.3	Must be suitable for adults 18 years and older		
3.4	The unit must use the oscillometric method of measurement.		
3.5	Pressure measurements:		
3.6	Adult: Systolic: 30 - 270 mm Hg, Diastolic: 20 - 240 mm Hg, colour coding to be considered		
3.7	Auto zero when unit is switched on		
3.8	Over pressure protection: Automatic deflation at 300 mm Hg adult (error to be displayed in LCD)		
3.9	Average measurement time: approximately 30 s or less		
3.10	If measurement exceeds two minutes the cuff must deflate, an alarm must sound and likely faults indicated.		
3.11	The air hose must be at least 1 metre long.		
3.12	LCD Display:		
3.12.1	The display must offer clear viewing under all lighting conditions , (display to include backlight)		
3.12.2	The following must be displayed:		
3.12.2a	Systolic, diastolic pressures		
3.12.2b	Visual indication(colour codes) for lower, normal, high and critically high blood pressure		
3.12.2c	Battery status		
3.14.2d	Indication of mains power or battery operation		

3.13	ALARMS:		
3.13.1	All alarms must have default settings		
3.13.2	Violation of limits must result in both audible and/ visual alarms and indication of the parameters affected.		
3.13.3	Low battery: Alarm or visual indication at least 10 minutes before battery power is exhausted		
3.14	Other system requirements		
3.14.1	The unit must operate from 220 V, 50 Hz mains supply adapter		
3.14.2	Adapter cable at least two metres long with SABS approved 15A three prong plug.		
3.14.3	The unit must include an internal lithium rechargeable battery.		
3.14.4	The unit must be able to function from the mains supply regardless of the battery condition.		
3.14.5	Rechargeable battery must have the capacity for the unit to operate fully for at least five hours		
3.14.6	The rechargeable battery must be charged while the unit is operating from the mains supply (lithium batteries).		
3.14.7	The battery must automatically take over in the event of a mains power failure.		
3.14.8	The case of the unit must be robust and impact resistant.		
3.14.9	The design must be such that spilled liquids do not gain access to the internal working of the unit.		
3.14.10	The monitor must be compact and stable to operate on the table or handheld.		
3.14.11	The unit must be handed over in full operating order/fully functional		
3.14.12	A starter-pack of consumables must be supplied with the unit.		
4	Standard Consumables		
4.1	1x Reusable latex-free small adult cuff		
4.2	2 x Reusable latex-free standard adult cuff		
4.3	1 x Reusable latex-free obese cuff		
4.4	1 x NIBP hose		
4.5	1 x Adapter /Standard SABS compliant Plug		
4.6	1 x Carry bag, and a set of rechargeable lithium batteries for operation of the BP machine and separate charger if not onboard charging (built-in on-board preferable)		

5	Conformity Compliance (Please attach certificate)		
5.1	The unit must comply with an acceptable international electrical safety standard such as IEC 601-1 for medical equipment, attach certification		
5.2	OEM must comply and be certified on ISO 13485 quality standards, attach proof of compliance		
5.2.1	Please provide unique ref number of the ISO 13485 certificate:		
5.3	Model quoted for must be EC certified or equivalent. Attach a copy of certification		
5.3.1	Please provide unique ref number of the EC certificate:		
5.4	The equipment quoted for must be protected against electromagnetic interference IEC 60601-1-2		
6	COMPREHENSIVE MAINTENANCE		
6.1	A 24 month warranty inclusive maintenance and service/Replacement (Year 1 to Year 2) should be quoted for, as per the SCC document		
6.1.1	THIS ENTAILS: A 2-year warranty against poor workmanship and latent defects and parts. This must be all inclusive and include, BUT NOT LIMITED TO, amongst others, ALL PARTS (including Batteries), Labour, Traveling and Accommodation. The 2-year warranty must also include all quality check, quality assurance requirements, Preventative Maintenance/Calibrations, Software updates and upgrades to be included. This 2-year warranty will commence after formal Commissioning and handover of the equipment.		
7	General		
7.1	Has the product on offer being on safety recall by the Regulatory Authority in the last 5 years? If yes, please provide further details of the recall and how was it addressed		
7.2	The unit on offer must be the latest technology.		
8	Mandatory/replacement accessories (pricing to be made available for future procurement)		
8.1	1x Reusable latex-free small adult cuff		
8.2	1 x Reusable latex-free standard adult cuff		
8.3	1 x Reusable latex-free obese cuff		

8.4	1 x NIBP hose
8.5	1 x Adapter
8.6	1x Rechargeable lithium battery

	Haemoglobin Meter	Complies Yes/No	Provide your answers/comments in this Column. You are advised to be straight to the point.
1	DESCRIPTION		
1.1	This specification establishes the requirements, supply, delivery, end user training, demonstration, installation and commissioning of a portable Haemoglobin meter able to measure accurate results covering the whole measurement range of ≤ 4.5 - ≥ 26 g/dl (0-26 g/dl or 0-16 mmol/l)		
2	Product Offered:		
2.1	Make:		
2.2	Model:		
2.3	Initial Manufacturing year of Model:		
3	SPECIFICATIONS		
3.1	The unit offered must be robust, lightweight, compact and user friendly.		
3.2	The unit must be accurate. Shorlisted units will undergo a trial as part of evaluation.		
3.3	Bider to provide the following regarding the unit:		
3.4	Number of test results that can be stored: Onboard memory: 1000 tests		
3.5	Operating conditions: 10 - 40 degrees celcius; relative humidity: 35 - $<90\%$		
3.6	Storage conditions: 0 - 50 degrees celcius, relative humidity: $< 90\%$		
3.7	Minimum sample volume 10 - 20 microlitres		
3.8	Weight (in grams)		
3.9	The unit must be able to analyze capillary, venous or arterial whole blood		
3.10	Time to obtain results: ≤ 30 seconds)		
3.12	The unit must be battery/electrically operated (re-chargeable or Alkaline batteries)		
3.13	The unit must have a built in memory to record the measurements.		
3.14	The unit must be supplied with a carry case for protection.		

3.15	The unit must be operated without any additional eye protection for both the user and patient		
3.16	The meter must have a digital display which is visible under all lighting conditions		
3.17	The unit must be able to display haemoglobin test in g/l, g/dl and mmol/l		
3.18	The above units must be user selectable as per their preference		
3.17	With measurement range of ≤ 4.5 - ≥ 26 g/dl or/and 0 - 16 mmol/L		
3.18	The Unit should be provided complete with all accessories for operation.		
3.19	The unit must be Factory calibrated and have built-in auto self calibration		
3.20	Automatic shutdown if not in use: < 6 minutes		
4	Standard Accessories and Consumables		
4.1	Carry case/bag for safe-keeping		
4.2	Battery (alkaline/lithium rechargeable batteries)		
4.3	Test strips (Pk of 50)		
4.4	Bluetooth, USB and/or other data transfer options		
4.5	Single-use disposable lancets		

5	Conformity Compliance (Please attach certificate)		
5.1	The unit must comply with an acceptable international electrical safety standard such as IEC 601-1 for medical equipment, attached certification		
5.2	OEM must comply and certified on ISO 13485 quality standards, attach proof of compliance		
5.2.1	Please provide unique ref number of the ISO 13485 certificate:		
5.3	Model quoted for must be EC certified. Attach a copy of certification		
5.3.1	Please provide unique ref number of the EC certificate:		
6	COMPREHENSIVE MAINTENANCE		
6.1	A 24 month warranty inclusive maintenance and service (Year 1 to Year 2) must be included in the bid price		

6.1.1	<p>THIS ENTAILS: A 2-year warranty against poor workmanship and latent defects and parts. This must be all inclusive and include, BUT NOT LIMITED TO, amongst others, ALL PARTS (including Batteries), Labour, Traveling and Accommodation. The 2-year warranty must also include all quality check, quality assurance requirements, Preventative Maintenance/on-board Calibrations, Software updates and upgrades to be included.</p> <p>This 2-year warranty will commence after formal Commissioning and handover of the equipment</p>		
7	General		
7.1	Has the product on offer being on safety recall by the Regulatory Authority in the last 5 years? If yes, please provide further details of the recall and how was it addressed		
7.2	The unit on offer must be the latest technology.		
8	MANDATORY Accessories and Consumables (pricing to be made available for future procurement)		
8.1	Battery (alkaline/lithium rechargeable batteries)		
8.2	Test Strips		
8.3	quality control Solutions		
8.4	Bidder to list any other Consumables or Accessories (Not listed above) for the model on offer below		
8.5	Single-use disposable lancets		

	Multi-parameter Machine	Complies Yes/No	Provide your answers in this Column. You are advised to be straight to the point.
1	DESCRIPTION		
1,1	Multi parameter testing machine with the following tests: ketones, cholesterol, lactate, uric acid		
2	Product Offered:		
2,1	Make:		
2,2	Model:		
2,3	Initial Manufacturing year of Model:		
3	SPECIFICATIONS		
3.1	The unit offered must be robust, lightweight, compact and user friendly.		
3.2	The unit must be accurate. Shortlisted units will undergo a trial as part of evaluation.		
4	Bider to provide the following regarding the unit:		
4.1	Memory Capacity: minimum 100 patients (Data to be captured and uploaded)		
4.2	Approximate Dimensions: Bidders to supply information		
4.3	Unit Must have Bluetooth or other Wireless equivalent		
4.4	Unit must have USB/micro		
4.5	Operating Conditions: 8°C~45°C, relative humidity:10%-90%		
4.6	Storage Conditions: -20 °C ~ +60 °C (Meter); 2°C ~ 30°C (Strips)		
4.7	Approximate weight: Bidders to supply information		
4.8	The unit must be battery operated (rechargeable lithium/alkaline battery).		
4.9	Accuracy: A minimum of 1 local correlation trials minimum)(Proof to be supplied for model of machine) Specificity and sensitivity should correlate with laboratory-based results. Bidder must be SAHPRA licensed for medical device		
4.10	The unit must be supplied with a carry case for protection.		
4.11	The meter must have a digital display which is visible under all lighting conditions		
5	KETONE		
5.1	Enzyme type:HBD		
5.2	Sample size: 0.8 µL		
5.3	Reaction Time: 10 seconds		
5.4	Measurement Range: 0.1 ~ 8.0 mmol/L		
5.5	Hematocrit Range: 10% - 70%		
5.6	Precision: 1 mmol/L, SD < 0.1 mM; > 1 mmol/L, CV < 7.5%		
5.7	Package: Vial pack 50		
6	TOTAL CHOLESTEROL		
6.1	Sample size: 3.0 µL		
6.2	Reaction Time: 60 seconds		
6.3	Measurement Range: 100 ~ 400 mg/dL		
6.4	Hematocrit Range: 20% - 60%		
6.5	Precision: CV < 7.5%		
6.6	Package: Vial Pack 50		
7	URIC ACID		
7.1	Sample size:0.5 µL		
7.2	Reaction Time: 15 seconds		
7.3	Measurement Range:3-20 mg/dL (178-1190 µM)		
7.4			
7.5	Hematocrit Range: 20% - 60%		
7.6	Precision: 5 mg/dL, SD<0.5 mg/dL; >5 mg/dL, CV<7.5% (Û297 µM, SD<30 µM; >297 µM, CV<7.5%)(Û0.29 mM, SD<0.03 mM; >0.29 mM, CV<7.5%)		
7.7	Package: Vial pack 50		
8	LACTATE		
8.1	Sample size: 0.8 µL		
8.2	Reaction Time: 5 seconds		
8.3	Measurement Range: 0.3 - 22 mmol/L		
8.4	Hematocrit Range: 10% - 65%		
8.5	Precision: Û3mmol/L, SD<0.3mM; >3mmol/L, CV<7.5%		
8.6	Package: Vial pack 50		
9	Standard Accessories and Conusmables		
9.1	Battery		
9.2	Test Strips per test parameter (Pk of 50)		

9.3	The unit on offer must be the latest technology.		
10	Conformity Compliance (Please attach certificate)		
10.1	The unit must comply with an acceptable international electrical safety standard such as IEC 61010-1 for medical equipment, attached certification		
10.2	Original Equipment Manufacturer (OEM) must comply and certified on ISO 13485 quality standards, attach proof of compliance		
10.3	Please provide unique ref number of the ISO 13485 certificate:		
10.4	Model quoted for must be EC certified. Attach a copy of certification		
10.5	Please provide unique ref number of the EC certificate:		
10.6	OEM must comply and certified on ISO 15197:2013 quality standards, attach proof of compliance		
10.7	Please provide unique ref number of the ISO 15197:2013 certificate:		
11	COMPREHENSIVE MAINTENANCE		
11.1	A 24 month warranty inclusive maintenance and service (Year 1 to Year 2) must be included in the bid price/ Replacement		
11.2	THIS ENTAILS: A 2-year warranty against poor workmanship and latent defects and parts. This must be all inclusive and include, BUT NOT LIMITED TO, amongst others, ALL PARTS (including Batteries), Labour, Traveling and Accommodation. The 2-year warranty must also include all quality check, quality assurance requirements, Preventative Maintenance/Calibrations, Software updates and upgrades to be included. This 2-year warranty will commence after formal Commissioning and handover of the equipment		
12	General		
12.1	Has the product on offer being on safety recall by the Regulatory Authority in the last 5 years? If yes, please provide further details of the recall and how was it addressed		
12.2	The unit on offer must be the latest technology.		
13	MANDATORY Accessories and Consumables		
13.1	Battery		
13.2	Test Strips		
13.3	quality control Solutions		
13.4	Bidder to list any other Consumables or Accessories or Software (Not listed above) for the model on offer below		

	Dual Glucose HBA1c Meter	Complies Yes/No	Provide your answers in this Column. You are advised to be straight to the point.
1	DESCRIPTION		
1.1	Portable dual handheld analyser with the following tests: Glucose and HBA1C		
2	Product Offered:		
2.1	Make:		
2.2	Model:		
2.3	Initial Manufacturing year of Model:		
3	SPECIFICATIONS		
3.1	The unit offered must be robust, lightweight, compact and user friendly.		
3.2	Shorlisted units will undergo a trial as part of verification		
3.3	Bidder to provide the following regarding the unit:		
3.4	Memory Capacity: minimum100 patients		
3.5	Approximate Dimensions: Companies to supply		
3.6	unit must have Bluetooth or other Wireless equivalent		
3.7	Unit must have USB/micro		
3.8	Operating conditions: Glucose: 5-40°C, 10%-90% R.H HbA1c: 10-40°C, 30%-75% R.H		
3.9	Storage conditions : -20 °C ~ +55 °C (Meter); 2°C ~ 30°C (Strips) HbA1c: 4°C ~ 30°C		
3.10	Approximate weight: Company to supply		
3.11	The unit must be battery operated. Batteries must be Lithium based Rechargable /alkaline		
3.12	Accuracy: A minimum of 1 local correlation trials minimum)(Proof to be supplied for model of machine)Specificity and sensitivity should correlate with laboratory-based results. Bidder must be SAHPRA licensed for medical device		
3.13	The unit must be supplied with a carry case for protection.		
3.14	The meter must have a digital display which is visible under all lighting conditions		
4	Glucose		

4.1	Sample size: 0.8 µL		
4.2	Reaction Time: max 10 seconds		
4.3	Measurement Range: 0.6~33.3 mmol/L		
4.4	Precision: ≥5.55 mmol/L, bias≤+15%		
4.5	Package: Vial pack 50		
5	HBA1C		
5.1	Sample size: 3.0 µL		
5.2	Reaction Time: max 7 minutes		
5.3	Measurement Range: 4.0%-14.0% 20.2-129.5 mmol/mol eAG: 67.9-354 mg/dL		
5.4	Precision: CV < 5%		
5.5	Package: Vial Pack 50		
5.6	Standard Accessories and Consumables		
5.7	Battery		
5.8	Test Strips per test parameter (Pk of 50)		
5.9	The unit on offer must be the latest technology.		
5.11	Conformity Compliance (Please attach certificate)		
5.12	The unit must comply with an acceptable international electrical safety standard such as IEC 61010-1 for medical equipment, attached certification		
5.13	OEM must comply and certified on ISO 13485 quality standards, attach proof of compliance		
5.14	Please provide unique ref number of the ISO 13485 certificate:		
5.15	Model quoted for must be EC certified. Attach a copy of certification		
5.16	Please provide unique ref number of the EC certificate:		
5.17	COMPREHENSIVE MAINTENANCE		
5.18	A 24 month warranty inclusive maintenance and service (Year 1 to Year 2) must be included in the bid price/ Replacement		

5.19	<p>THIS ENTAILS: A 2-year warranty against poor workmanship and latent defects and parts. This must be all inclusive and include, BUT NOT LIMITED TO, amongst others, ALL PARTS (including Batteries), Labour, Traveling and Accommodation. The 2-year warranty must also include all quality check, quality assurance requirements, Preventative Maintenance/Calibrations, Software updates and upgrades to be included.</p> <p>This 2-year warranty will commence after formal Commissioning and handover of the equipment.</p>		
5.20	General		
5.21	Has the product on offer being on safety recall by the Regulatory Authority in the last 5 years? If yes, please provide further details of the recall and how was it addressed		
5.22	The unit on offer must be the latest technology.		
5.23	Mandatory Accessories and Consumables		
5.24	Battery		
5.25	Test Strips		
5.26	quality control Solutions		
5.27	Bidder to list any other Consumables or Accessories (Not listed above)		
6	Software :		
6.1	Bidders to supply downloadable/installable software on smart mobile/computer devices as the endusers may require. This should be compatible with bluetooth/USB or other equivalent means of data transfer/capture. Shortlisted Bidders will be required to demonstrate the software interface to the Bid Evaluation Committee		
6.2.	Key features of the software should at minimum include:		
6.2.1	Type of Test(Glucose,HbA1C ...etc)		
6.2.2	Patient Name or Identifier		

6.2.3	Health Care worker Name or Identifier		
6.2.4	Permissions for different Health Care Workers/Doctor		
6.2.5	Locations(Clinic/district/province... etc)		
6.2.6	Short Report/intervention/s		
6.2.7	Date and Time		

	HbA1c Meter	Complies Yes/No	Provide your answers in this Column. You are advised to be straight to the point.
1	DESCRIPTION		
1,1	Portable /handheld HbA1c test analyser		
2	Product Offered:		
2,1	Make:		
2,2	Model:		
2,3	Initial Manufacturing year of Model:		
3	SPECIFICATIONS		
3.1	The unit offered must be robust, lightweight, compact and user friendly.		
3.2	Shorlisted units will undergo a trial as part of verification		
3.3	Bidder to provide the following regarding the unit:		
3.4	Memory Capacity: minimum100 patients		
3.5	Approximate Dimensions: Bidders to supply		
3.6	unit must have Bluetooth or other wireless equivalent		
3.7	Unit must have USB/micro		
3.8	Operating conditions: 10-40°C, 30%-75% R.H		
3.9	Storage conditions : 4°C ~ 30°C(Room temperature)		
3.10	Approximate weight: bidders to supply		
3.11	The unit must be battery operated. (Rechargable /alkaline)		
3.12	Accuracy: A minimum of 1 local correlation trials minimum)(Proof to be supplied for model of machine)Specificity and sensitivity should correlate with laboratory-based results. Bidders must be SAHPRA licenced for supply of medical devices		
3.13	The unit must be supplied with a carry case for protection.		
3.14	The meter must have a digital display which is visible under all lighting conditions		
4	HBA1C		

4.1	Sample size: 3.0 µL		
4.2	Reaction Time: max 7 minutes		
4.3	Measurement Range: 4.0%-15.0% 20-140 mmol/mol eAG: 67.9-354 mg/dL		
4.4	Package" strips package of 50		
4.5	Test Strips to be compatible with dual meter		
5	Standard Accessories and Consumables		
5.1	Battery		
5.2	Test Strips (Pk of 50)		
5.3	The unit on offer must be the latest technology.		
6	Conformity Compliance (Please attach certificate)		
6.1	The unit must comply with an acceptable international electrical safety standard such as IEC 61010-1 for medical equipment, attached certification		
6.2	OEM must comply and certified on ISO 13485 quality standards, attach proof of compliance		
6.3	Please provide unique ref number of the ISO 13485 certificate:		
6.4	Model quoted for must be EC certified. Attach a copy of certification		
6.5	Please provide unique ref number of the EC certificate:		
7	COMPREHENSIVE MAINTENANCE		
7.1	A 24 month warranty inclusive maintenance and service (Year 1 to Year 2) must be included in the bid price/ Replacement		

7.2	<p>THIS ENTAILS: A 2-year warranty against poor workmanship and latent defects and parts. This must be all inclusive and include, BUT NOT LIMITED TO, amongst others, ALL PARTS (including Batteries), Labour, Traveling and Accommodation. The 2-year warranty must also include all quality check, quality assurance requirements, Preventative Maintenance/Calibrations, Software updates and upgrades to be included.</p> <p>This 2-year warranty will commence after formal Commissioning and handover of the equipment.</p>		
8	General		
8.1	Has the product on offer being on safety recall by the Regulatory Authority in the last 5 years? If yes, please provide further details of the recall and how was it addressed		
8.2	The unit on offer must be the latest technology.		
9	Mandatory Accessories and Consumables		
9.1	Battery		
9.2	Test Strips		
9.3	quality control Solutions		
9.4	Bidder to list any other Consumables or Accessories (Not listed above)		

	Glucose meter	Complies Yes/No	Provide your answers in this Column. You are advised to be straight to the point.
1	DESCRIPTION		
1,1	Portable Glucose testing device		
2	Product Offered:		
2,1	Make:		
2,2	Model:		
2,3	Initial Manufacturing year of Model:		
3	SPECIFICATIONS		
3.1	The unit offered must be robust, lightweight, compact and user friendly.		
3.2	Shorlisted units will undergo a trial as part of verification		
3.3	Bidder to provide the following regarding the unit:		
3.4	Memory Capacity: minimum100 patients		
3.5	Approximate Dimensions: Companies to supply		
3.6	unit must have Bluetooth		
3.7	Unit must have USB/micro		
3.8	Operating conditions: Glucose: 5- 45°C, 10%-90% R.H		
3.9	Storage conditions : -20 °C ~ +55 °C (Meter); 2°C ~ 32°C (Strips)		
3.10	Approximate weight: Bidders to supply		
3.11	The unit must be battery operated. Battery must be Rechargeable/ Alkaline		

3.12	Accuracy: A minimum of 1 local correlation trials minimum)(Proof to be supplied for model of machine)Specificity and sensitivity should correlate with laboratory-based results. Bidders must be SAHPRA licensed		
3.13	The unit must be supplied with a carry case for protection.		
3.14	The meter must have a digital display which is visible under all lighting conditions		
4	Glucose		
4.1	Sample size: 0.8 µL		
4.2	Reaction Time: max 10 seconds		
4.3	Measurement Range: 0.6~33.3 mmol/L		
4.4	Package: Strips pack of 50		
4.5	Strips to be compatible with dual meter		
5.	Standard Accessories and Consumables		
5.1	Battery		
5.2	Test Strips (Pk of 50)		
5.3	The unit on offer must be the latest technology.		
6	Conformity Compliance (Please attach certificate)		
6.1	The unit must comply with an acceptable international electrical safety standard such as IEC 61010-1 for medical equipment, attach certification		

6.2	OEM must comply and certified on ISO 13485 quality standards, attach <u>proof of compliance</u>		
6.3	Please provide unique ref number of the ISO 13485 certificate:		
6.4	Model quoted for must be EC certified. Attach a copy of <u>certification</u>		
6.5	Please provide unique ref number of the EC certificate:		
7	COMPREHENSIVE MAINTENANCE		
7.1	A 24 month warranty inclusive maintenance and service (Year 1 to Year 2) must be included in the bid <u>price/ Replacement</u>		
7.2	<p>THIS ENTAILS: A 2-year warranty against poor workmanship and latent defects and parts. This must be all inclusive and include, BUT NOT LIMITED TO, amongst others, ALL PARTS (including Batteries), Labour, Traveling and Accommodation. The 2-year warranty must also include all quality check, quality assurance requirements, Preventative Maintenance/Calibrations, Software updates and upgrades to be included.</p> <p>This 2-year warranty will commence after formal Commissioning and handover of the equipment.</p>		
8	General		

8.1	Has the product on offer being on safety recall by the Regulatory Authority in the last 5 years? If yes, please provide further details of the recall and how was it addressed		
8.2	The unit on offer must be the latest technology.		
9	Mandatory Accessories and Consumables		
9.1	Battery		
9.2	Test Strips		
9.3	quality control Solutions		
9.4	Bidder to list any other Consumables or Accessories (Not listed above)		

	Cholesterol Meter	Complies Yes/No	Provide your answers in this Column. You are advised to be straight to the point.
1	DESCRIPTION		
1,1	Testing machine For Cholesterol		
2	Product Offered:		
2,1	Make:		
2,2	Model:		
2,3	Initial Manufacturing year of Model:		
3	SPECIFICATIONS		
3.1	The unit offered must be robust, lightweight, compact and user friendly.		
3.2	The unit must be accurate. Shorlisted units will undergo a trial as part of evaluation.		
4	Bider to provide the following regarding the unit:		
4.1	Memory Capacity: minimum 100 patients (Data to be captured and uploaded)		
4.2	Approximate Dimensions: Bidders to supply		
4.3	Unit Must have Bluetooth /other equivalent wireless connectivity		
4.4	Unit must USB/micro		
4.5	Operating Contitions: 8°C-45°C, 10%-90% R.H		
4.6	Storage Conditions: -20 °C ~ +60 °C (Meter); 2°C ~ 30°C (Strips)		
4.7	Approximate weight: Bidders to supply information		
4.8	The unit must be rechargeable lithium/alkaline battery operated.		
4.9	Accuracy: A minimum of 1 local correlation trials minimum)(Proof to be supplied for model of machine) Specificity and sensitivity should correlate with laboratory-based results. Bidder must be SAHPRA licensed for medical device		
4.10	The unit must be supplied with a carry case for protection.		

4.11	The meter must have a digital display which is visible under all lighting conditions		
5	TOTAL CHOLESTEROL		
5.1	Sample size: 3.0 µL		
5.2	Reaction Time: 60 seconds		
5.3	Measurement Range: 100 ~ 400 mg/dL		
5.4	Precision: CV < 7.5%		
5.5	Package: Vial Pack 50		
5.6	Test strips to be compatible with multi-parameter machine		
6	Standard Accessories and Consumables		
6.1	Lithium /Rechargeable Battery /alkaline batteries		
6.2	Test Strips per test parameter (Pk of 50)		
6.3	The unit on offer must be the latest technology.		
7	Conformity Compliance (Please attach certificate)		
7.1	The unit must comply with an acceptable international electrical safety standard such as IEC 61010-1 for medical equipment, attached certification		
7.2	OEM must comply and certified on ISO 13485 quality standards, attach proof of compliance		
7.3	Please provide unique ref number of the ISO 13485 certificate:		
7.4	Model quoted for must be EC certified. Attach a copy of certification		
7.5	Please provide unique ref number of the EC certificate:		
7.6	OEM must comply and certified on ISO 15197:2013 quality standards, attach proof of compliance		
7.7	Please provide unique ref number of the ISO 15197:2013 certificate:		
8	COMPREHENSIVE MAINTENANCE		
8.1	A 24 month warranty inclusive maintenance and service (Year 1 to Year 2) must be included in the bid price/ Replacement		

8.2	<p>THIS ENTAILS: A 2-year warranty against poor workmanship and latent defects and parts. This must be all inclusive and include, BUT NOT LIMITED TO, amongst others, ALL PARTS (including Batteries), Labour, Traveling and Accommodation. The 2-year warranty must also include all quality check, quality assurance requirements, Preventative Maintenance/Calibrations, Software updates and upgrades to be included.</p> <p>This 2-year warranty will commence after formal Commissioning and handover of the equipment</p>		
9	General		
9.1	Has the product on offer being on safety recall by the Regulatory Authority in the last 5 years? If yes, please provide further details of the recall and how was it addressed		
9.2	The unit on offer must be the latest technology.		
10	Mandatory accessories and consumables		
10.2	Rechargable battery		
10.2	Test Strips		
10.3	Quality control Solutions		
10.4	Bidder to list any other Consumables or Accessories (Not listed above) for the model on offer		

	Ketones Meter	Complies Yes/No	Provide your answers in this Column. You are advised to be straight to the point.
1	DESCRIPTION		
1,1	Testing machine for Ketones		
2	Product Offered:		
2,1	Make:		
2,2	Model:		
2,3	Initial Manufacturing year of Model:		
3	SPECIFICATIONS		
3.1	The unit offered must be robust, lightweight, compact and user friendly.		
3.2	The unit must be accurate. Shortlisted units will undergo a trial as part of evaluation.		
4	Bider to provide the following regarding the unit:		
4.1	Memory Capacity: minimum 100 patients (Data to be captured and uploaded)		
4.2	Approximate Dimensions: Bidders to supply		
4.3	Unit Must have Bluetooth or Equivalent wireless connectivity		
4.4	Unit must USB/micro		
4.5	Operating Conditions: 8°C~45°C, 10%-90% R.H		
4.6	Storage Conditions: -20 °C ~ +60 °C (Meter); 2°C ~ 32°C (Strips)		
4.7	Approximate weight: Bidders to supply		
4.8	The unit must be battery operated. (rechargeable lithium/alkaline?)		

4.9	Accuracy: A minimum of 1 local correlation trials minimum)(Proof to be supplied for model of machine) Specificity and sensitivity should correlate with laboratory-based results. Bidder must be SAHPRA licensed for medical device		
4.10	The unit must be supplied with a carry case for protection.		
4.11	The meter must have a digital display which is visible under all lighting conditions		
5	KETONE		
5.1	Enzyme type:HBD		
5.2	Sample size: 0.8 µL		
5.3	Reaction Time: 10 seconds		
5.4	Measurement Range: 0.1 ~ 8.0 mmol/L		
5.6	Precision: 1 mmol/L, SD < 0.1 mM; > 1 mmol/L, CV < 7.5%		
5.7	Package: strips pack 50		
5.8	Test strips to be compatible with multi-parameter machine		
6	Standard Accessories and Consumables		
6.1	Rechargeable /alkaline Battery		
6.2	Test Strips per test parameter (Pk of 50)		
6.3	The unit on offer must be the latest technology.		
7	Conformity Compliance (Please attach certificate)		
7.1	The unit must comply with an acceptable international electrical safety standard such as IEC 61010-1 for medical equipment, attached certification		
7.2	OEM must comply and certified on ISO 13485 quality standards, attach proof of compliance		
7.3	Please provide unique ref number of the ISO 13485 certificate:		
7.4	Model quoted for must be EC certified. Attach a copy of certification		
7.5	Please provide unique ref number of the EC certificate:		

7.6	OEM must comply and certified on ISO 15197:2013 quality standards, attach proof of compliance		
7.7	Please provide unique ref number of the ISO 15197:2013 certificate:		
8	COMPREHENSIVE MAINTENANCE		
8.1	A 24 month warranty inclusive maintenance and service (Year 1 to Year 2) must be included in the bid price/ Replacement		
8.2	THIS ENTAILS: A 2-year warranty against poor workmanship and latent defects and parts. This must be all inclusive and include, BUT NOT LIMITED TO, amongst others, ALL PARTS (including Batteries), Labour, Traveling and Accommodation. The 2-year warranty must also include all quality check, quality assurance requirements, Preventative Maintenance/Calibrations, Software updates and upgrades to be included. This 2-year warranty will commence after formal Commissioning and handover of the equipment		
9	General		
9.1	Has the product on offer being on safety recall by the Regulatory Authority in the last 5 years? If yes, please provide further details of the recall and how was it addressed		
9.2	The unit on offer must be the latest technology.		
10	Mandatory Accessories and Consumables		
10.1	Rechargeable /alkaline Battery		
10.2	Test Strips		
10.3	quality control Solutions		
10.4	Bidder to list any other Consumables or Accessories (Not listed above) for the model on offer below		