

## Quotation Advert

Opening Date:

05/03/2024

Closing Date:

11/03/2024

Closing Time:

11:00

INSTITUTION DETAILS

Institution Name:

King Edward VIII Hospital

Province:

KwaZulu-Natal

Department of entity:

Department of Health

Division or section:

Central Supply Chain Management

Place where goods/ service is required: King Edward Hospital

Date Submitted:

04/03/2024

ITEM CATEGORY AND DETAILS

Quotation number:

KEV595/23

Item Category:

Goods

Item Description:

Horizontal cone beam CT scanner re-advertised

Quantity (if supplies):

01 Units

COMPULSORY BRIEFING SESSION / SITE VISIT

Select Type:

Not applicable

Date:

Click here to enter a date.

Time:

Click here to enter text.

Venue:

QUOTES CAN BE COLLECTED FROM:

uploaded on website

QUOTES SHOULD BE DELIVERED TO:

Security tender box

ENQUIRIES REGARDING ADVERT MAY BE DIRECTED TO:

Name: RADEBE A.E

Email: N/A

Contact number: 031-360 3869

Finance Manager Name:

Mrs V. Mtantato

Finance Manager Signature



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#### OFFICIAL PRICE PAGE FOR QUOTATIONS OVER R2 000.01

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NAME OF BIDE	DER:		SIGNATURE OF B		and a second	and an dition	



#### 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 othics as enshrined in the Constitution of the Republic of South Africa and further expressed in various pieces of logislation, 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 DECLARA	ATION
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- 2.1. Is the bidder, or any of its directors / trustees / shareholders / members / partners or any person having a controlling interest in the enterorise, employed by the state?
- 2.1.1. If so, furnish particulars of the names, individual identity numbers, and, if applicable, state employee numbers of sole proprietor/ directors / trustees /

FULL NAME	IDENTITY NUMBER	NAME OF STATE INSTITUTION

2.2.	Do you, or any person connected with the bidder,	have a relationship with any person who is employed by the procuring institution?	YES /	ŀ	VC
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- 2.2.1. If so, furnish particulars:
- 2.3. Does the bidder or any of its directors / trustees / shareholders / members / portners 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?
- 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 consortium? 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
- 3.5. 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.
- 3.6. There have been no consultations, communications, agreements or arrangements made by the bidder with any official of the procuring 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.
- 3.7. 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 PEMA SCM INSTRUCTION 03 OF 2021/22 ON PREVENTING AND COMBATING ABUSE IN THE SUPPLY CHAIN MANAGEMENT SYSTEM SHOULD THIS DECLARATION PROVE TO BE FALSE.

NAME OF BIDDER	SIGNATURE	POSITION	DATE	Ξ

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

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



#### GENERAL CONDITIONS OF CONTRACT

#### 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 verse and words in the masculine also mean in the feminine and neuter.

- The General Conditions of Contract will form part of all bid/quotation 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 provail.

#### 1 Definitions

- 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 tabour, 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.freesury.gov.zo



#### 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. Falling 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 projudice 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
- 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

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 14.1. 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.
- 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 produce 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 ontitled 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 falls 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 antidumping 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 amount whichmay be due to him.

#### 25 Force Majeure

- 25.1. Notwithstanding the provisions of GGC 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 whatsoover 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.
- 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
  - (h) 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 flable 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 (imitation 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

- 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.
- 31.2. The time mentioned in the contract documents for performing any act after such aforesald notice has been given, shall be reckaned from the date of posting of such notice.

#### 32 Taxes and duties

- 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.
- 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.
- 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.

#### 33 National Industrial Participation (NIP) Programme

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

- 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).
- 34.2. If a bidder(s) or contractor(s), based on reasonable grounds or evidence obtained by the purchasor, 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.
- 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.



#### SPECIAL CONDITIONS OF CONTRACT

#### 1. AMENDMENT OF CONTRACT

1.1. Any amendment to or renunciation of the provisions of the contract shall at all times be done in writing and shall be signed by both parties.

#### 2. CHANGE OF ADDRESS

2.1. Bidders must advise the Department of Health (institution where the offer was submitted) should their address (domicilium chandi et executandi) details change from the time of bidding to the expiry of the contract.

#### 3. GENERAL CONDITIONS ATTACHED TO THIS QUOTATION

- The Department is under no obligation to accept the lowest or any quote.
- 3.2. The Department reserves the right to communicate in writing with vendors in cases where information is incomplete or where there are obscurities regarding technical aspects of the offer, to obtain confirmation of prices or preference claims in cases where it is evident that a typing, written, transfer or unit error has been made, to investigate the vendor's standing and ability to complete the supply/service satisfactorily.
- 3.3 ALL DECISIONS TAKEN BY THE DEPARTMENT ARE FINAL, INCLUDING THE AWARD OR CANCELLATION OF THIS QUOTATION.
- 3.4. The price quoted must include VAT (if VAT vendor).
- 3.5. Should a bidder become a VAT vendor after award or during the implementation of a contract, they may not request the VAT percentage from the Department as the service provider made an offer during the period they were not registered as a VAT vendor. The Department is only liable for any VAT from registered VAT vendors as originally stated on the quotation document.
- 3.6. The bidder must ensure the correctness & validity of the quotation:
  - (i) that the price(s), rate(s) & preference quoted cover all for the work/item (s) & accept that any mistakes regarding the price (s) & calculations will be at the bidder's risk;
  - (ii) it is the responsibility of the bidder to confirm receipt of their quotation and to keep proof thereof.
- 3.7. The bidder must accept full responsibility for the proper execution & fulfilment of all obligations conditions devolving on under this agreement, as the Principal (s) liable for the due fulfilment of this contract.
- 3.8. This quotation will be evaluated based on the 80/20 points system, specification, correctness of information and/or functionality criteria. All required documentation must be completed in full and submitted.
- 3.9. Offers must comply strictly with the specification.
- Only offers that meet or are greater than the specification will be considered.
- 3.11. Late offers will not be considered.
- 3.12. Expired product/s will not be accepted. All products supplied must be valid for a minimum period of six months.
- 3.13. Used/ second-hand products will not be accepted.
- 3.14. A bidder not registered on the Central Suppliers Database or whose verification has failed will not be considered.
- 3.15. All delivery costs must be included in the quoted price for delivery at the prescribed destination.
- 3.16. Only firm prices will be accepted. Such prices must remain firm for the contract period. Non-firm prices (including rates of exchange variations) will not be considered.
- 3.17. In cases where different delivery points influence the pricing, a separate pricing schedule must be submitted for each delivery point.
- 3.18. In the event of a bidder having multiple quotes, only the cheapest according to specification will be considered.
- 3.19. Verification will be conducted to identify if bidders have multiple companies and are cover-quoting for this bid.
- 3.20. In such instances, the Department reserves the right to immediately disqualify such bidders as cover-quoting is an offence that represents both corruption and acquisition fraud.

#### 4 SPECIAL INSTRUCTIONS AND NOTICES TO BIDDERS REGARDING THE COMPLETION OF THIS QUOTATION.

- 4.1. Unless inconsistent with or expressly indicated otherwise by the context, the singular shall include the plural and vice versa and with words importing the masculine gender shall include the feminine and the neuter.
- 4.2. Under no circumstances whatsoever may the quotation/bid forms be retyped or redrafted. Photocopies of the original bid documentation may be used, but an original signature must appear on such photocopies.
- 4.3. The bidder is advised to check the number of pages and to satisfy himself that none are missing or duplicated.
- 4.4. Quotations submitted must be complete in all respects. However, where it is identified that information in a bidder's response, which does not affect the preference points or price, is incomplete in any respect, the said supplier meets all specification requirements and scores the highest points in terms of preference points and price, the Department reserves the right to request the bidder to complete/ submit such information.
- 4.5. Any alteration made by the bidder must be initialled; failure to do so may render the response invalid.
- 4.5. Use of correcting fluid is prohibited and may render the response invalid.
- 4.7. Quotations will be opened in public as soon as practicable after the closing time of quotation.
- Where practical, prices are made public at the time of opening quotations.
- 4.9. If it is desired to make more than one after against any individual item, such offers should be given on a photocopy of the page in question. Clear indication thereof must be stated on the schedules attached.
- 4.10. The Department is under no obligation to pay suppliers in part for work done if the supplier can no longer for fulfil their obligation.

#### 5. SPECIAL INSTRUCTIONS REGARDING HAND DELIVERED QUOTATIONS

- 5.1. Quotation shall be lodged at the address indicated not later than the closing time specified for their receipt, and in accordance with the directives in the quotation documents.
- 5.2. Each quotation shall be addressed in accordance with the directives in the quotation documents and shall be lodged in a separate sealed envelope, with the name and address of the bidder, the quotation number and closing date indicated on the envelope. The envelope shall not contain documents relating to any quotation other than that shown on the envelope. If this provision is not complied with, such quotations/bids may be rejected as being invalid.
- 5.3. All quotations received in scaled envelopes with the relevant quotation numbers on the envelopes are kept unopened in safe custody until the closing time of the quotation/bids. Where, however, a quotation is received open, it shall be sealed. If it is received without a quotation/bid number on the envelope, it shall be opened, the quotation number saceriained, the envelope scaled and the quotation number written on the envelope.
- 5.4. A specific box is provided for the receipt of quotations, and no quotation found in any other box or elsewhere subsequent to the closing date and time of quotation will be considered.



5.6. Quotation documents must not be included in packages containing samples. Such quotations may be rejected as being invalid.

#### SAMPLES

- 6.1. In the case of the quote document stipulating that samples are required, the supplier will be informed in due course when samples should be provided to the institution. (This decreases the time of safety and storage risk that may be incurred by the respective institution). The bidders sample will be retained if such bidder wins the contract.
  - (i) If a company/s who has not won the quote requires their samples, they must advise the institution in writing of such.
  - (ii) If samples are not collected within three months of close of quote the institution reserves the right to dispose of them at their discretion.
- 6.2. Samples must be made available when requested in writing or if stipulated on the document.
  - If a Bidder fails to provide a sample of their production offer for scrutiny against the set specification when requested, their offer will be rejected. All
  - (i) testing will be for the account of the bidder.

#### 7. COMPULSORY SITE INSPECTION / BRIEFING SESSION

7.1. Bidders who fail to attend the compulsory meeting will be disqualified from the evaluation process.

(i)	The institution	n has determi	ned that a compu	Isory site meeting Will	nottake pl	lace.	
(ii) - (	)ate:	1	1	Time:	3	Place:	
Institution Star	np:				Institution 8	Site Inspection / briefing session Official:	
					Full Name:		
					Signature:		
					Date:	8	

#### 8. STATEMENT OF SUPPLIES AND SERVICES

8.1. The contractor shall, when requested to do so, furnish particulars of supplies delivered or services executed. If he/she falls to do so, the Department may, without prejudice to any other rights which it may have, institute inquiries at the expense of the contractor to obtain the required particulars.

#### 9. SUBMISSION AND COMPLETION OF SBD 6.1

9.1. Should a bidder wish to qualify for preference points they must complete a SBD 6.1 document. Failure by a bidder to provide all relevant information required, will result in such a bidder not being considered for preference point's allocation. The preferences applicable on the closing date will be utilized. Any changes after the closing date will not be considered for that particular quote.

#### 10 TAX COMPLIANCE REQUIREMENTS

- 10.1. In the event that the tax compliance status has failed on CSD, it is the suppliers' responsibility to provide a SARS pin in order for the institution to validate the tax compliance status of the supplier.
- 10.2. In the event that the institution cannot validate the suppliers' tax clearance on SARS as well as the Central Suppliers Database, the quote will not be considered and passed over as non-compliant according to National Treasury Instruction Note 4 (a) 2016/17.

#### 11 TAX INVOICE

- 11.1. A tax invoice shall be in the currency of the Republic of South Africa and shall contain the following particulars:
  - (i) the name, address and registration number of the supplier;
  - (ii) the name and address of the recipient:
  - (iii) an individual serialized number and the date upon which the tax invoice
  - (iv) a description and quantity or volume of the goods or services supplied;
  - (v) the official department order number issued to the supplier;
  - (vi) the value of the supply, the amount of tax charged;
  - (vii) the words tax invoice in a prominent place.

#### 12 PATENT RIGHTS

12.1. The supplier shall indemnify the KZN Department of Health (hereafter known as 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.

#### 13. PENALTIES

- 13.1. If at any time during the contract period, the service provider is unable to perform in a timely manner, the service provider must notify the institution in writing/email of the cause of and the duration of the delay. Upon receipt of the notification, the institution should evaluate the circumstances and, if deemed necessary, the institution may extend the service provider's time for performance.
- 13.2. In the event of delayed performance that extends beyond the delivery period, the institution is cutified to purchase commodities of a similar quantity and quality as a substitution for the outstanding commodities, without terminating the contract, as well as return commodities delivered at a later stage at the service provider's expense.
  Alternatively, the institution may elect to terminate the contract and procure the necessary commodities in order to complete the contract. In the event
- 13.3. Alternatively, the institution may elect to terminate the contract and produce the nucessary commodities in order to complete the contract. In the event that the contract is terminated the institution may claim damages from the service provider in the form of a penalty. The service provider's performance should be captured on the service provider database in order to determine whether or not the service provider should be awarded any contracts in the future.
- 13.4. If the supplier falls 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.



#### 14. TERMINATION FOR DEFAULT

- 14.1. 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:
  - (i) if the supplier falls to deliver any or all of the goods within the period(s) specified in the contract,
  - (ii) if the supplier fails to perform any other obligation(s) under the contract; or
  - (iii) if the supplier, in the judgment of the purchaser, has engaged in corrupt or fraudulent practices in competing for or in executing the contract.
- 14.2. 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.
- 14.3. 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.
- 15. THE DEPARTMENT RESERVES THE RIGHT TO PASS OVER ANY QUOTATION WHICH FAILS TO COMPLY WITH THE ABOVE.



SBD 6.1.

#### 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. The applicable preference point system for this tender is the 80/20 preference point system.
- 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. The maximum points for this tender are allocated as follows:

	POINTS
PRICE	80
SPECIFIC GOALS	20
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.

#### 4. 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:

80/2

 $Ps = 80 \left( 1 - \frac{Pt - Pmin}{Pmin} \right)$ 

OR

1

 $Ps = 90 \left( 1 - \frac{Pt - Pmin}{Projection} \right)$ 

90/10

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:

80/20

 $Ps = 80 \left(1 + \frac{Pt - Pmax}{r}\right)$ 

OR

 $Ps = 90 \left( 1 + \frac{Pt - Pmax}{Pmax} \right)$ 

90/10

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 heliow as may be supported by prooff 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 tenderers: The tenderer must indicate how they claim points for each preference point system.

	The specific goal/s allocated points in terms of this tender	Number of points allocated (80/20 system)	Number of points <u>claimed</u> (80/20 system)
Promo	tion of South African owned enterprises	20	
	DECLARATION WITH REGARD TO COMPANY/FIRM		
4.3.	Name of company/firm:		
4.4.	Company registration number:		
4.5.	TYPE OF COMPANY/ FIRM [tick applicable box]  Partnership/Joint Venture / Consortium  One-person business/sole propriety  Close corporation  Public Company  Personal Liability Company  (Pty) Limited  Nun-Profit Company  State Owned Company		
4.6.	<ul> <li>I, the undersigned, who is duly authorised to do so on behalf of the company/firm, certify that the points claimed, based on the in the tender, qualifies the company/ firm for the preference(s) shown and I acknowledge that:</li> <li>i) The information furnished is true and correct;</li> <li>ii) The preference points claimed are in accordance with the General Conditions as indicated in paragraph 1 of this form;</li> <li>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 documentary proof to the satisfaction of the organ of state that the claims are correct;</li> <li>iv) If the specific goals have been claimed or obtained on a fraudulent basis or any of the conditions of contract have not bee state may, in addition to any other remedy it may have — <ul> <li>(a) disqualify the person from the tendering process;</li> <li>(b) recover costs, losses or damages it has incurred or suffered as a result of that person's conduct;</li> <li>(c) cancel the contract and claim any damages which it has suffered as a result of having to make less favourable arran cancellation;</li> <li>(d) recommend that the tenderer or contractor, its shareholders and directors, or only the shareholders and directors where side) rule has been applied; and</li> <li>(e) forward the matter for criminal prosecution, if deemed necessary.</li> </ul> </li> </ul>	may be required the germents due to a cled on a fr	ed to furnish organ of o such audulent
	SIGNATURE(S) OF TENDERER(S)  SURNAME AND NAME:  DATE:  ADDRESS:	**	

# health Department:

Signature

Standard End-User Specification Form

Date

## **END-USER SPECIFICATION FORM**

P .	ROL NCE OF KWAZULU-NATAL	,		
Quo	te Number:	CEV 595/23		
ltem	Description HORIZONT	AL CONE BEAM SCANNER		
CAI	PACITY			
Dep any:	and the state of t	BLOCK THEATRE	P	urpose of : qualification criteria if
	1.1 le the item require	to have a regulatory hody or	ertification (e.a. SABS SANS	SANAS, ISO, CIDB, etc.)? Yes:
		ation required if Yes:		
	rregulatory body r dertilled	ation required in 1 co.		
	1.2. Is a compulsory sit if Yes, specify: Date	te inspection / briefing sessio	n required?/ No Place	
		and content part of the quote		
		ion 4(1)(a) of the PPPFA Regu		es / No
	/ C			
	1.5. Liability Cover insu	urance / Yes / No		
	if Yes, specify.			
2.	What is the specification	on of the required item?		
	specifications to be adver		C	omment
1.	AS PER ATTACHED HT	C ODECIEICATION		
2.	100 × 500 100 × 50 10 × 50 00 00 00 00 00 00 00 00 00 00 00 00			
-				
3.				
4.				
3. or	3.1. Deadline for submis	be submitted? Yes / No(select ssion if Yes: Date// es must be made available wher	Time:Place _	or No
4.	contract, the purcha as a penalty, a sur	to deliver any or all of the go aser shall, without prejudice to it	s other remedies under the cor price of the delayed goods or	es within the period(s) specified in the ntract, deduct from the contract prior unperformed services using the current formance.
5.	What is the evaluation	criteria / special terms and co	nditions to be advertised?	
		al terms and conditions to be ac	lvertised (if applicable)	
1.	Pre-qualification criteria	Does the offer meet the pre-q	ualification criteria?	
2.	Administrative		lated administrative requiremen	
3.	Conformance:		rice performed to specifications	
4.	Performance:	from all liabilities under the co	ntract?	in a manner that releases the supplie
5.	Features:	What characteristics does the		
6.	Reliability:	How long can a product go be	tween failures and the need fo	r maintenance? (guarantee)
7.	Durability:	What is the useful life for the	product? How will the product h	old up under extended use?
8.	Serviceability:		ain or support the product or se	
9.	Ability & Capacity		vendor to execute the contrac	t
10.	Preference points	Preferential Procurement Sys	tem (80/20) if applicable	
61	and at Flagh course Star E.IIIV	04 = 04 4	Name of SCM Rep (in fu	III) I De Augustus
100012	me of End-user (in full)	MZ Majola		
De	signation / Rank (in full)	Om w	Designation/ Rank (in fu	III) SUID

Signature

Date

08/09/1023 Page 1 of 2

# PROVINCE OF KWAZULU-NATAL

### DEPARTMENT OF HEALTH

# HEALTH TECHNOLOGY SERVICES (H.T.S. – RADIOLOGY SERVICES)

SPECIFICATION FOR: CONE BEAM CT SCANNER FOR DENTAL USE

SPECIFICATION: RAD 28 - (RADIOLOGY)

NB: GENERAL CLAUSES THAT DO NOT APPLY TO THE EQUIPMENT OFFERED MUST BE ANSWERED "COMPLIES", "DOES NOT COMPLY" OR ANSWER THE QUESTION UNDER BIDDERS COMMENTS.

	T	
		BIDDERS COMMENTS:
NO	SPECIFICATION	STATE "COMPLIES" OF "DOES NOT COMPLY" OR ANSWER THE QUESTION.
Clause G1	The space provided under "Bidder's Comments" for each clause must be used for this purpose. Bidders who neglect to provide answers to every Clause in this Bid Specification will be disqualified. Bidders must note that abbreviated answers e.g. N/A etc. will not be accepted. Bidders must also note that no part of any clause/s in this Bid Specification may be altered. Where there are traces of alterations found to any clauses in this Bid Specification during Adjudication, the Adjudication Committee will reserve the right to disqualify the bidder.  The Bidder must clearly indicate if their offered product complies with the stated requirements, by indicating, "Complies" or "Does not comply" or answer the question next to the corresponding clause.	
Clause G2	All responses must be clear and legible.	1
Clause G3	GUARANTEE:	
Clause G3.1	All Equipment, Materials and Workmanship provided under this Contract must be Guaranteed for a minimum period of twenty four (24) Months. The successful bidder must arrange with the respective Hospital / Institution and the Health Technology Services before Commissioning the Equipment at the respective Hospital / Institution.  The bidder to note that the Guarantee period must only take effect upon successful Commissioning at the respective Hospital / Institution and successful test and acceptance by the Health Technology Services.	
Clause G3.2	State percentage guaranteed up time of machine (Should be at least 99%).	
Clause G3.3	The recommended number of services, per annum, by the manufacturer, must be included during and up until the end of the guarantee period and all costs related to the provision of such service/s will be for the bidders account.	
Clause G3.4	The bidder must state the number of services that will be provided during and up to the end of the guarantee period.	
Clause G3.5	Any breakdown during the guarantee period must include all cost (spares, labour, travelling and sundries) for any prescribed maintenance services (major and minor) as well as any QA testing that is required by Department Health's Radiation Control Board during the guarantee period.	
Clause G3.6	Travelling and Travelling Time costs must be included during the Guarantee Period?	
Clause G3.7	Spares that may be required during the Guarantee Period will be supplied at the expense of the bidder.	
Clause G3.8	Downtime during the Guarantee Period must extend the Guarantee time on a Day-to-Day basis.	
Clause G3.9	Any repetition (twice or more) of the same type of fault that first occurred during the guarantee period must be considered as a repair under guarantee if it occurs within the first year after the expiry of the guarantee period.	
Clause G3.10	The same guarantee conditions must apply to replacement units.	
Clause G4	The successful bidder must Supply, Deliver, Commission and install the Equipment and will be required to demonstrate the product to the applicable Staff at the Institution and costs for the abovementioned must be included in the final bid price.	
Clause G5	Bidders must offer the Health Technology Service's In House Technicians a demonstration of the product, which will enable the Health Technology Service's In House Technicians to become acquainted with the equipment during the Test and Acceptance phase.	
Clause G6	Preference may be given to a make and model that has been technically and clinically evaluated by a Government Institution within the R.S.A. (Attach	

		BIDDERS COMMENTS
NO	SPECIFICATION	STATE "COMPLIES" O "DOES NOT COMPLY" OR ANSWER THE QUESTION.
Clause G7	proof of evaluation where applicable).	
Clause G7	The successful bidder must provide the Health Technology Service's in house Technicians, full training in the calibration, maintenance, service and repair of the product down to PCB Level. N.B. The quality and level of the training must be equivalent to the manufacturer's original factory training and any costs incurred to provide this training will be for the bidders account. A Certificate of Competency must be issued on completion of the training. The Training must be provided by the successful bidder to the Health Technology Services within three months from date of initial supply and delivery of the equipment to the end user.	
Clause G8	SERVICING:	
Clause G8.1	The bidder must have a well established service and repair facility in KwaZulu-Natal, to service,repair and calibrate the equipment offered. (The Health Technology Services reserves the right to inspect the premises).	
Clause G8.2	If the service is subcontracted to a local service agent, a signed copy of the letter of appointment by the bidder and acceptance by the subcontractor must be submitted with this bid / quotation. (The Health Technology Services reserves the right to inspect the premises).	
Clause G8.3	State Number of other medical equipment "Repair & Service" Agencies (excluding your Agency) represented by the subcontractor.	
Clause G8.4	Supply the Name, Address and Telephone Number/s of the Local Service Department within KwaZulu-Natal.	
	Please supply details as follows:  Company name	
	Physical Address :  Telephone Number/s :	
	Fax number :	
	(The Health Technology Services reserves the right to inspect the premises).	
Clause G8.5	State if the Technician(s) are in the direct employ of the bidder or a subcontractor.	
Clause G8.6	The bidder must supply information on the number of Technicians	
	permanently working in KwaZulu-Natal and their names and contact Telephone Number/s must be listed (Directly employed or subcontracted) in an annexure to the bid document.	
Clause G8.7	The Technician(s) must be original equipment manufacturer trained to deal with the service, repair and calibration of the equipment quoted on.  N.B. Proof of original equipment manufacturer training must be submitted with this bid / quotation offer.	
Clause G8.8	The Institution's requirement is that a technician is available within a reasonable time (24 hours) to attend to malfunctioning equipment. The Bidder to state the technician per install base e.g. equipment ratio to	

		BIDDERS COMMENTS
NO	SPECIFICATION	STATE "COMPLIES" C "DOES NOT COMPLY" OR ANSWER THE QUESTION.
Clause G9	technician ratio, e.g. 1 technician per 10 pieces of equipment.  The bidder must Guarantee that no additional equipment will be required for the successful operation of the equipment bided for on delivery and commissioning at the customers site. A starter pack of all essential accessories and disposables must be supplied so that the unit can be put into immediate operation. The cost of the starter pack must be included in the final bid price.	
Clause G10	Optional accessories must be offered for separately on the Schedule of optional accessories found at the end of this Technical specification, indicating catalogue numbers, correct descriptions and Prices inclusive of V.A.T.	
Clause G11	Bidder must state the period of time for delivery of Spare parts following the receipt of an official order as follows: 0 to 10 days; 0 to 20 days; 0 to 30 days; 0 to 60 days; 0 to 90 days; more than 90 days.	
Clause G11.1	The Bidder must supply with this offer a list together with the quantities of spares held locally in stock in the KwaZulu-Natal Province on the offered product. The Health Technology Services reserves the right to inspect the premises to verify the spares stock held	
Clause G12	The bidder must include a firm commitment in writing, which must be attached with this bid that they would supply spares, components, upgrades, complete original service / repair manual, technical support and ongoing training support for technical staff of the Health Technology Services and the end users Department of Health, KwaZulu-Natal throughout the life cycle of the equipment offered.	
Clause G13	Spares must be available for 10 (Ten) years from the original equipment manufacturer for the product offered.	
Clause G14	The successful bidder must include in their offer at no extra cost to the final bid price:	
Clause G14.1	Complete user Operation / Maintenance Manual x 2 (two) Book / File; CD; DVD copies in English Language.	
Clause G14.2	Complete ORIGINAL Service / Repair Manual x 2 (two) Book / File; CD; DVD copies in English Language which MUST include the following information: Fault Finding Guide, Circuit Diagrams / Schematics, Circuit Descriptions, and PCB Layouts, Calibration Guide, Part Numbers and exploded diagram of Mechanical Parts / Panels.	
Clause G14.3	All the above Manuals must be properly bound in either a Book, File or CD form.	
Clause G14.4	The Bidder must supply all software (including software-keys and / or passwords) to allow for trouble shooting (faultfinding), maintenance, calibrations, repairs and services at no additional cost.	
Clause G15	Does your Company have an after hour service back up facility.	
Clause G16	If the equipment is taken away for repairs, a loan set must be made available on request to the end user by the Institution until the Institution's unit is returned. All costs incurred for providing the loan unit must be for the bidders account.	
Clause G17	Bidder must bid on the latest model and Technology that fully complies with this Technical Specification.	
Clause G17.1	The Bidder must state how long this technology has been commercially available (state when the model offered was launched)	
Clause G17.2	The bidder must state if there are any near future updates expected.	
Clause G18	The successful bidder must maintain a system for notifying and providing	

		BIDDERS COMMENTS
NO	SPECIFICATION	STATE "COMPLIES" O "DOES NOT COMPLY" OR ANSWER THE QUESTION.
Clause G19	users with Updates, Modifications, new Software Releases and Recalls.  The successful bidders must arrange for an acceptance test of the equipment with the Manager of the Health Technology Services and the Hospital Manager. A copy of the original answered Specification, copy of the invoice order and relevant paperwork (PH form) from the receiving Hospital must be submitted with the equipment when the ACCEPTANCE TEST is to be undertaken.	
Clause G20	Where equipment bided for, operates off 220 Volt, 50Hz a.c. supply, bidder must ensure that the product being quoted for is fitted with a 15 Amp approved mains plug top, which is held together by two screws.	
Clause G21	The unit must comply with an acceptable International Electrical Safety Standard such as IEC 60601-1 and 60601-1-2 for Medical Equipment where	
Clause G22	the quoted equipment operates off an electrical supply.  All equipment, the installation and any alteration / additions must comply with:	
Clause G22.1	The Occupational Health and Safety Act (1993);	
Clause G22.2	The wiring code S.A.N.S. 0142.	
Clause G23	Units being quoted for must be CE Certified. (Attach a copy of certification). The make and the model offered must be reflected on the certificate.	
Clause G24	The Mains Cable of the unit being quoted for must be the Hospital Grade Type and it must be a minimum length of (3) three metres. N.B. The mains cable of the unit being quoted for must be S.A.N.S. colour coded.	
Clause G25	The equipment being quoted for must be protected against Electro magnetic Interference.	
Clause G26	Only new equipment must be quoted for. Refurbished and reconditioned equipment being quoted on will not be accepted.	
Clause G27	Bidders must note that dedicated test equipment, spare parts and any special tooling required for the upkeep and maintenance of the equipment quoted on must be available to the Health Technology Services to procure if requested.	
Clause G28	All the necessary calibration and maintenance software, where applicable, required to maintain and calibrate the equipment, must be supplied with the equipment to the Health Technology Services at no extra cost to the final bid price.	
Clause G29	NB. HAZARDOUS SUBSTANCE ACT:	CALLS AS IN
Clause G29.1	If this type of equipment / apparatus appears on the schedule of Hazardous Substances issued by the Directorate: Health Technology of the Department of Health, a license in terms of the Act on Hazardous Substances (Act. 15/1973) must be submitted with this bid document. The license must be registered under the bidders name or a letter of joint venture must be submitted by the license holder where the license is not in the name of the bidder. Bidders that neglect to submit a license will not be considered.	
Clause G29.2	Bidder must state the Radiation Control licence number of the make and model of equipment offered.	License No:
Clause G29.3	Where it has been established by the bidder that the equipment offered does not require Radiation Control licence, proof from the Radiation Control authority must be submitted with this bid document.	
Clause G30	The system offered must comply fully with or exceed all of the minimum specification requirements per the Technical Clauses.	
Clause G31	The offer submitted must be supported by descriptive literature, colour pamphlets, colour brochures and technical data sheets applicable to the	

The second second		
		BIDDERS COMMENTS
NO	SPECIFICATION	STATE "COMPLIES" OF "DOES NOT COMPLY" OR ANSWER THE QUESTION.
	offer (i.e. supporting information for all components of the system) must accompany the bid, failing which the bid will not be considered.	
Clause G32	The equipment and any accessories ordered from the successful bidder will be delivered, installed, tested, calibrated, demonstrated (including specified training) and commissioned in the specific Hospital at the expense of the successful Bidder, prior to full payment being made.	
Clause G33	All prices are to include V.A.T. and must be quoted in the South African currency. The price must be valid for a period of 180 days from closing date of bid.	
Clause G34	If the product offered is unknown to the Department, the Department reserves the right to have the unit evaluated by a team of Technical and Clinical experts with regards to its functionality, performance and quality. The decision of this committee will be used as a motivation for the evaluation and recommendation of the bid. For this reason a demonstration unit must be readily available within14 days, or the bidder must take arrange for demonstration with representatives of the Department for the equipment offered at a site within South Africa where a same make and model of unit is installed and is in full clinical operation. The cost of this site visit is for the account of the bidder and it must therefore not place any obligation on the Department to procure from the bidder.	
Clause G35	The Institution requesting the unit reserves the right to clinically trial and evaluate the unit in order to ensure that the unit meets the clinical requirements of the Department before adjudication of the bid.	
Clause G36	UPGRADEABILITY WHERE APPLICABLE:	
Clause G36.1	Bidders are to state the policy with regard to future software updates and the costs that will be involved.	
Clause G36.2	The Bidder to state what hardware and software will be available, with costs and projected dates.	
Clause G37	UPGRADE POLICY:	
Clause G37.1	All future upgrades (hardware and software) involving patient safety must be offered at no additional cost.	
Clause G37.2	All future upgrades removing software viruses from existing software must be supplied at no cost.	
Clause G37.3	Any upgrade before or after installation of the equipment involving additional cost must be brought to the attention of the Manager, Health Technology Services.	
Clause G38	The Bidder must indicate the expected life of their offered unit and software in years.	

TECHNICAL SPECIFICATION.			
Clause T1			
GENERAL			
Clause T1.1			
This specification establishes the requirements for the SUPPLY, DELIVERY, INSTALLATION, DEMONSTRATION and COMMISSIONING of a CONED BEAM CT SCANNER FOR DENTAL USE			
BIDDER'S COMMENTS:			
Clause T1.2			
The bid price quoted must include the supply, installation, demonstration and commissioning of the equipment as well as the building alterations that may be required for the successful installation of the units.			
BIDDER'S COMMENTS:			
Clause T2			
SCANNER REQUIREMENTS:			
The Scanner must have the following requirements:			
PHYSICAL DIMENSIONS			
Length 110.5 in (280.6 cm) *docked Width 32.0 in (81.3 cm)			
Height 79.6 in (202.2 cm) *gantry door open			

SPECIFICATION: H.T.S. RAD-28 (RADIOLOGY)
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Weight 2046 lbs (925.8 Kg) Gantry Opening 27.5 in (69.9 cm) Bore Diameter 38 in (96.5 cm)

## IMAGING MODALITY PERFORMANCE

Single Plane 2D Pulsed fluoroscopy at 30 frames/second

Multi Plane 2D Up to four 2D images, from pre-set positions

#### Standard 3D Volumetric:

Data Acquisition: • < 16 seconds -Standard: 14seconds

Number of Projections: • 391 images over 360°

3D Reconstruction Time; • < 30 seconds - Standard: 7seconds

Field of View (FOV) option: • 20cm Resolution (mm): • 0.415 x 0.415 x 0.833 Reconstructed Matrix Size: • 512 x 512 x 192

#### High Definition 3D Volumetric

Data Acquisition: • < 30seconds -Standard: 27seconds

Number of Projections: • 745 images over 360°

3D Reconstruction Time: • < 30 seconds -Standard for 20cm FOV: 23seconds -Standard for 40cm FOV: 23seconds Field of View (FOV) options: • 20cm • 40cm

Resolution (mm): • 20cm FOV: 0.415 x 0.415 x 0.833 • 40cm FOV: 0.775 x 0.775 x 0.833

Reconstructed Matrix Size: • 512 x 512 x 192

#### Low Dose 3D Volumetric

Data Acquisition: • < 16 seconds -Standard: 14seconds

Number of Projections: • 391 images over 360°

3D Reconstruction Time: • < 90 seconds -Standard: 65seconds Field of View option: • 20cm Resolution (mm): • 0.415 x 0.415 x 0.833

Reconstructed Matrix Size: • 512 x 512 x 192

#### Enhanced Cranial 3D Volumetric

Data Acquisition: • < 30 seconds -Standard: 27seconds

Number of Projections: • 745 images over 360°

3D Reconstruction Time: • < 30 seconds -Standard: 13seconds

Field of View (FOV) option: • 20cm Resolution (mm): • 0.415 x 0.415 x 0.833 Reconstructed Matrix Size: • 512 x 512 x 192

#### Stereotaxy 3D Volumetric

Data Acquisition: • < 30 seconds -Standard: 27seconds

Number of Projections: • 745 images over 360°

3D Reconstruction Time: • < 30 seconds -Standard: 13seconds

Field of View (FOV) option: • 40 cm Resolution (mm): • 0.775 x 0.775 x 0.833

Reconstructed Matrix Size: • 512 x 512 x 192

#### 3D IMAGING VOLUME

Cylindrical Volume

20 cm FOV: 21.25 cm diameter x 15 cm high 40 cm FOV: 39.70 cm diameter x 15 cm high

Resolution

20 cm FOV (mm): 512 x 512 x 192 40 cm FOV (mm): 512 x 512 x 192

#### 2D IMAGE ENHANCEMENTS

Edge enhancement 7 settings Recursive noise reduction Automatic Auto-brightness control Yes Auto window/Level Yes

Region of Interest- User Selectable Full field of regional dose control Yes

#### X-RAY TUBE

Varian® Model B100 (rotating anode) with A132 insert; generator is max rated at 32KW

#### X-RAY DETECTOR

Varian® Model Paxscan® 4030D 2.0K x 1.5K, pixel pitch of 0.194mm amorphous silicon COLLIMATION • X-Y axis shutters • Electronically controlled by user • Dynamically adjustable filter set • 3D collimation also available POWERASSISTED TRANSPORT • 1.5 max MPH power drive system • Independent rear wheel drive • Handle-controlled

ROBOTIC MOTION CONTROLS (movement speeds) Linear gantry motion X and Y-axis: 5 inches/second Z-axis: 2.5 inches/second Rotational Wag 4° per second Rotational Tilt 7.5° per second Gantry Door (open/close) 8° per second Gantry rotor (internal) 60° per second (max.) Note: Gantry linear movement speed can be slowed ten-fold by pressing the [M] button on the pendant. ROBOTIC MOTION CONTROLS (movement ranges from docked position) Linear gantry, Vertical: ±9 inches (±0.125 inches), ±22.9 (±0.32 cm) • 17.25 inches total \*Y-axis gas springs account for decrease of 0.75 inches Linear gantry, Transverse: ±9 inches, ±22.9cm • 18 inches total (45.8cm) Linear gantry, Longitudinal: ±7 inches (±0.25in), ±17.8 (±0.64 cm) • 14 inches total Rotational Wag ±15° Rotational Iso-wag® ±12° (nominal) Rotational Tilt ±45°

#### ENVIRONMENTAL SPECIFICATIONS OPERATING

Temperature 10° 30° C Humidity 0-80% RH Non-condensing Vibration: Frequency g value Amplitude No open vibration Shock: g value pulse Duration No open shock STORAGE AND TRANSPORTATION Temperature -10° to 40° C Humidity 10-80% RH Non-condensing Vibration: Frequency 0.01 g-squared/Hz @ 4 – 100 Hz tapered to 0.001 squared/Hz @ 200 Hz

POWER REQUIREMENTS VAC 100 to 240 VA FREQUENCY 50/60 Hz POWER REQUIREMENTS 1440 VA

X-RAY SOURCE ASSEMBLY TUBE TYPE Varian A132 (rotating anode) HOUSING TYPE B100 TUBE RATING 150 kV FOCAL SPOT Dual: The nominal focal spot values according IEC 60336 are: For small focal spot: • Width = 0.60 mm to 0.90 mm • Length = 0.90 mm to 1.30 mm For large focal spot: • Width = 1.20 mm to 1.70 mm • Length = 1.7 mm to 2.4 mm INHERENT FILTRATION 0.7mm AI ADDED FILTRATION Additional filtration was added to beam for a total: > 4mm AI LEAKAGE TECHNIQUE FACTORS 150kV, 3.3mA ANODE HEAT STORAGE CAPACITY 300kHU (222 kJ) HOUSING HEAT STORAGE CAPACITY 1,250kHU (927 kJ)

X-RAY GENERATOR ASSEMBLY GENERATOR RANGE GENERATOR RANGE ACCURACY ACCURACY Power 32 KW Max - kVp Reproducibility - <= 0.05 CV mAs Linearity -

PULSED EXPOSURE MODE kVp 40-140 kVp (in 1 kVp Steps)  $\pm 10\%$  mA 10, 12.5, 16, 20, 25, 32, 40, 50, 63, 80,  $100 \pm 20\%$  Exposure Time Per Pulse 10 msec  $\pm 10\% + 1$  msec PULSED FLUORO MODE kVp 40 - 125kVp (in 1kVp steps)  $\pm 10\%$  mA Reported Value  $\pm 20\%$  Exposure Timer Per Pulse 10 msec  $\pm (10\% + 1$ msec)

KV:

98

MA:

3 mA - 6 mA

Imaging Volume:

15 cm spherical imaging volume

Field of view:

5 - 17 x 5 - 13.5 cm

3D resolution:

Isotropic voxel size

0.25 / 0.125 mm

Scan time:

12 s - 28 s (+/- 10%)

Exposure time

2-5s

Effective dose (Ludlow):

20 uSv - 500 uSv

Operation:

Easy pad

Patient positioning:

Standing / seated Chin rest / bite block

Forehead support and head fixation

Floor stand:

Yes

Wheelchair appropriate:

Yes

Remote control:

Yes

Face scanner

Yes

Computer Requirements :

Viewing

2 GHz Intel Duo Core

2 GHz Intel Duo Core

Acquisition

RAM:

CPU:

4GB

8GB

Hard disk drive:

1.2 GB for software installation

installation

4 GB for software

250 GB free space to use the software

the

software

Graphic board:

with

2D - PCI Express based card with 2D -

PCI Express based card

250 GB free space to use

minimun 512 MB

minimun 512 MB

3D - NVIDIA based graphic card

3D - NVIDIA based graphic card with minimun 2 GB

CUDA 3 compatible, minimun 200 CUDA cores

Monitor:

19 inch or larger

19 inch or larger

resolution of

1280 x 1024, 32 - bit colour mode

Minimum screen resolution of

Minimun screen

1280 x 1024, 32 - bit colour

mode

Operating system: Windows / 64 Bit

Windows / 64 Bit

Ethernet interface: 1 Gbit for LAN

1 Gbit for system link

connection 1 Gbit for LAN

1 free PCIe slot required

Intel Pro 1000 CT

for

Bidder to Sign and Date every Page

SPECIFICATION: H.T.S. RAD-28 (RADIOLOGY) Page 10 of 14

CD / DVD drive:	A DVD burner
Back up media:	Removable / portable external hard disk drive
Mouse:	2 buttons and a scroll wheel
BIDDER'S COMM	ENTS:
_	
(a	
Clause T3	
The bid price mus	t include the necessary QA test, any additional items, modifications or building alterations he requirements of the Directorate Radiation Control of the Department of Health.
BIDDER'S COMME	
DIDDER G COMME	.141

FULLY COMPREHENSIVE MAINTENANCE CONTRACT
Clause 4.1
Bidders must provide a fully comprehensive maintenance and service agreement for a period of 5 years to commence upon termination of the warranty period of two years.
Clause 4.2
This contract would cover, but not be limited to the following: ALL PARTS (including, where appropriate, X-Ray tubes and other glassware), labour, traveling, accommodation, service and maintenance. The five year maintenance plan must also include all Quality Control and Quality Assurance requirements, including all required calibrations.
Clause 4.3
Software changes to the equipment which are corrective in nature and initiated due to software errors, regulatory requirements or safety reasons, shall be delivered and installed at no charge for the period of the contract.
Clause 4.4
The bidder must state the number of services per annum that are required for the equipment offered as per the manufacturer's recommendations and attach proof of this from the Original Equipment Manufacturer (OEM).
Clause 4.5
The bidder must complete the attached Service Level Agreement and detail costs on the Annexures provided in the Service Level Agreement.
BIDDER'S COMMENT

# SCHEDULE OF OPTIONAL ACCESSORIES

Bidder to Sign and Date every Page

Clause T4

Bidders must quote the price of the optional accessories and items listed as well as any other accessories that may be useful to the end users. The receiving Institutions may purchase individual accessories necessary for their particular Institution.

Cat No	Item Price including VAT	
18		8

#### **DETAILED TECHNICAL SPECIFICATION**

GENERAL INFORMATION REQUIRED

# FAILURE TO COMPLETE THIS PART WILL DISQUALIFY THE BIDDER

Make:	
Model Number / Part Number for:	
Country of Origin	
Final Bid / Quotation Price inclusive of V.A.T.	
The Bid Price must be firm for 180 Days	
Local (KwaZulu-Natal) Agent	
Delivery Period	
R S A Import Permit Holder	
BIDDER	
	DATE
ADDRESS	
b <del>r</del>	
TELEPHONE NO.	FAX NO
CONTACT PERSON(PLEASE PRINT)	





# **EC** Certificate

Full Quality Assurance System Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) (Devices in Class IIa, IIb or III)

No. G1 099130 0004 Rev. 00

Manufacturer:

Fussen Technology Co.,Ltd.

1F, 3# Building, Tongfuyu Industrial Zone, Taoyuan Street

Nanshan District 518055 Shenzhen

PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Digital Intraoral X-ray Imaging System, Digital Intraoral Imaging Plate System and Dental Computed Tomography X-ray

System

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

GZ1918506

Valid from:

2020-03-04

Valid until:

2024-05-26

Date.

2020-03-04

Christoph Dicks

Head of Certification/Notified Body

# DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES



MANUFACTURER:

Fussen Technology Co., Ltd.

3F, Building #B Minlida Industrial Building, Zone 4

Honghualing Industrial Zone, 1189 Liuxian Avenue Pingshan

Community, Taoyuan Street Nanshan District

518055 Shenzhen, Guangdong PEOPLE'S REPUBLIC OF CHINA

MEDICAL DEVICE:

Dental Computed Tomography x-ray System, Model: Dentrix 50

GMDN Code: 37613, UMDNS Code: 18032

CLASSIFICATION - ANNEX IX:

CLASS IIB, RULE 10

CONFORMITY ASSESSMENT ROUTE:

ANNEX II.3

WE, THE MANUFACTURER, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES;

ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER. THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

STANDARDS APPLIED: SEE ATTACHED LIST OF STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED.

NOTIFIED BODY:

TÜV SÜD PRODUCT SERVICE GMBH

RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER:

0123

(EC) CERTIFICATE(S):

EC REP

EUROPEAN REPRESENTATIVE:

Shanghai International Holding Corp. GmbH (Europe)

Add: Eiffestrasse 80, 20537 Hamburg, Germany

START OF CE-MARKING:

PLACE, DATE OF DECLARATION:

SIGNATURE:

JULY 28, 2022

Page 1 of 1

HON: GENERAL MUNIAGER

13	ISO 10993-5:2009	Biological evaluation of medical devices -Part 5: Tests for in vitro
14	ISO10993-10: 2010	深間Biological evaluation of medical devices 科式中部公司 0:Tests for irritation and delayed to be hypersensitivity