**P R O F O R M A**

**Request for Market Information (“RFI”) for
Supply of Analyzer, Point-Of-Care, Renal Function Test Device**

**to The Chinese Medicine Hospital of Hong Kong (“CMHHK”)**

**(CMHPO Ref.: HHB/H/24/17/3/3/3)**

To : Project Director (CMHPO)

 (Attn. Ms Stella CHEUNG)

[by fax: 2127 4795 or email: syhcheung@healthbureau.gov.hk]

Your ref: ( ) in L/M to HHB/H/24/17/3/3/3

In response to the RFI of the CMHHK, my/our company, with contact details provided in Part 1 below, would like to provide the information and relevant supporting documents in Parts 2 to 9 of this Proforma.

**Part 1 – Supplier’s Contact Details**

From:

(Name of the Supplier): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(please fill in)

Name and Post of Contact person: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(please fill in)

Email:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Telephone no.:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(please fill in) (please fill in)

**-----------------------------------------------------------------------------------------------------------------**

*This document does not constitute any offer or invitation / solicitation of any offer in connection with the exercise described herein. Neither this document nor any activities in connection therewith shall create any legal obligations or liabilities in any way on the part of the Health Bureau (HHB) or the Government of Hong Kong Special Administrative Region. Neither this document nor anything contained herein shall form the basis of any contract or commitment whatsoever. In responding to the RFI, a respondent shall be deemed to have agreed to all the terms of this Request for Market Information.*

**Purpose and Background Information of the RFI**

1. Purpose

Chinese Medicine Hospital Project Office (“**CMHPO**”) of the Health Bureau (“**HHB**”) of the Government intends to invite a tender for the supply of Analyzer, Point-Of-Care, Renal Function Test Device (hereinafter refers as the “**System**”) for the Chinese Medicine Hospital (“**opCMHHK**”) located at 1 Pak Shing Kok Road, Tseung Kwan O, New Territories, Hong Kong. The CMHPO therefore wishes to collect market information on the System.

1. Background of the CMHHK Project

The Chief Executive announced in the 2014 Policy Address that the Government had decided to reserve a site in Tseung Kwan O for setting up a CMHHK. The 2017 Policy Address stated that the Government decided to finance the construction of the CMHHK and identify by way of tender a suitable non-profit-making organisation (“NPMO”) to operate the CMHHK. CMHHK will be owned by the Government and the selected NPMO will operate the CMHHK. The CMHHK would be positioned as a flagship Chinese Medicine (“CM”) institution leading the development of CM services and Chinese medicines in Hong Kong. It will be a change driver, promoting service development, education and training, innovation and research, and facilitating collaboration with both local and international parties.

The CMHHK with provision of 400 beds will provide a comprehensive range of CM services. Service types include pure CM services, services with CM playing the predominant role in collaboration with Western Medicine (“WM”) and Integrated Chinese-Western Medicine (“ICWM”) services. The scope of service to be provided in the CMHHK covers inpatient, day-patient, outpatient and community outreach services.

To take forward the planning and development of the project on CMHHK, a designated office i.e. CMHPO, was established under the Health Bureau (the former Food and Health Bureau) on 2 May 2018. Hong Kong Baptist University (HKBU) was selected as the Contractor for the CMHHK operation. HKBU, as the Contractor, has incorporated a company limited by guarantee, namely HKBU Chinese Medicine Hospital Company Limited as the Operator to manage, operate and maintain the CMHHK. The CMHHK project has proceeded to the commissioning stage in 2021. It is targeted to commence hospital services by phases from 2025.

More information on the services provision and design of the CMHHK can be found in the following link:

<https://www.healthbureau.gov.hk/en/press_and_publications/otherinfo/200900_cmhp/index.html>

**Note to Suppliers**

1. If your company have more than one Analyzer, Point-Of-Care, Renal Function Test Device that may meet the requirements of the System stated in this Proforma, **please complete and return, together with relevant supporting documents, one set of Proforma for each different Analyzer, Point-Of-Care, Renal Function Test Device**.

**Part 2 – General Information of the System**

|  |  |
| --- | --- |
| 1. Place of origin
 |  |
| 1. Name of manufacturer
 |  |
| 1. Address of the manufacturer’s factory or plant (“Manufacturing Plant”)
 |  |
| 1. Product name of the System
 |  |
| 1. Model number/ name/ version number of the System
 |  |
| 1. Authorised agent or distributor of the manufacturer in Hong Kong
 |  |
| 1. Packing (if applicable)
 |  |
| 1. Delivery method and route (where the place of origin is outside Hong Kong)
 |  |
| 1. Warranty period of the System

(*Please refer to section F in Part 3 for details of the warranty service requirements*) | \_\_\_\_\_\_\_\_\_\_\_\_ months from Acceptance of the System(*Should not be less than 12 months*) |
| 1. Expected serviceable life (*Please specify any components of the System that cannot meet the serviceable life*)
 | The System shall have a serviceable life of \_\_\_\_\_\_\_ years from its date of acceptance except the following components: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(*Please also provide the expected life of these excluded components*) |

**Part 3 – Indicative Technical Requirements**

*Notes to Suppliers for Completion of Part 3*

1. *Unless specified otherwise, the “****System****” in this Part 3* ***refers to section A1.1 below****.*
2. *The indicative technical requirements are for the purpose of collecting market information only. They are subject to changes and do not represent the final technical requirements of the intended tender.*
3. *Please indicate, as a point by point compliance statement, whether your proposed System “****Comply****” or “****Not Comply****” with an indicative technical requirement stated in Column II by ticking (🗸) in the appropriate box under* ***Column III*** *and* ***Column IV*** *respectively.*
4. ***Where applicable****, please quote the value of your proposed System in either Column III (if “****Comply****”) or Column IV (if “****Not Comply****”) respectively against corresponding indicative technical requirement (use additional sheet(s) if space is insufficient*
5. *Please provide supporting documents (such as catalogues, user manual and/or operation manual, DICOM conformance statement, etc.) to illustrate the features of your proposed system against the corresponding indicative technical requirements.*

| **Column****I** | **Column** **II** | **Column** **III** | **Column****IV** |
| --- | --- | --- | --- |
| **Section** | **Technical Specification** | **Tick (🗸) the Appropriate Box***(For aspects “Not Comply”, please also provide alternative proposal, if any)* |
| **Comply** | **Not Comply** |
| **A** | **Technical Requirements** |
|  | **General Description** |
|  | The system shall call for the determination of renal function (with eGFR value), Blood Urea Nitrogen, Ionized Calcium and Lactate, in less than 100 microliters of human whole blood sample in bedside testing.  |  |  |
|  | The cartridge reader & monitor of device shall be non-detachable with all-in-one design and small handheld unit for easy-grip handling and transport between the clinical wards and shall weight less than 900 grams with battery. |  |  |
|  | The power supply shall be operated by rechargeable battery. The rechargeable battery shall be removed and replaced quickly without unfastening of screws. |  |  |
|  | The System shall compose of two units of analyser as identical mutual backup. |  |  |
|  |  |  |  |
|  | **Functional Requirements** |  |  |
|  | The analyzer shall have an internal electronic quality control test which can simulates electrical signals at three levels so as to provide an independent check on the ability of the analyzer to take accurate and sensitive measurements of voltage, current and resistance from the cartridge. The results *(Pass or Fail*) of the three levels of internal electronic QC test (related each specific test parameter e.g., Na+, K+, iCa etc.) shall be displayed and stored as a distinct record in the analyzer. |  |  |
|  | An automatic internal electronic quality control test shall be performed immediately without user intervention required after inserting each cartridge into the analyzer. |  |  |
|  | A reusable device for electronic QC test shall also be available and the operator can insert it into the device to run electronic QC test any time. |  |  |
|  | The analyzer shall consist of a built-in high-resolution camera bar-code scanning for data input. The image of barcode shall be shown on the screen of analyzer during scanning.  |  |  |
|  | The reference and action range settings shall be customized to program the analyzer to a specific care setting. |  |  |
|  | The analyzer shall have on-screen instruction.  |  |  |
|  | The analyzer shall be with sounds complement the lights to convey the results, which can alert operator when the results are ready. |  |  |
|  | The analyzer shall have the function of “Customizable Training Scenarios” which can provide specific scenarios for operation training and enables multiple instruments to generate identical results. |  |  |
|  | The analyzer shall automatically control all steps in the testing cycle including fluid movement within the cartridge, calibration, continuous quality monitoring and thermal control. |  |  |
|  | From cartridge preparation, applying blood sample and inserting cartridge into analyzer shall be in a single process without waiting. |  |  |
|  | Each testing cycle shall consist of running internal electronic QC test, calibration and patient test |  |  |
|  | The time of testing cycle (from cartridge insertion to test results coming out) shall not be more than 180 seconds for electrolytes analysis. |  |  |
|  | The patient test mode of analyzer (ready for inserting cartridge with patient blood sample) shall be stand-by 15 minutes for the operator to prepare sample and insert cartridge. If there is no cartridge insertion after 15 minutes, the analyzer will be turned off automatically |  |  |
|  | In order to prevent operator & patient ID entry errors of the analyzer, manual data entry shall be disabled and allow barcode scan data entry ONLY. |  |  |
|  | The cartridge shall be single use and disposable, and which employing micro-fabricated biosensors for the simultaneous quantitative determination of specific analytes in whole blood. |  |  |
|  | The sample inside the cartridge shall be pre-heated to 370C by built-in thermal heater before analysis. |  |  |
|  | The cartridge shall have a snap closure to capture and trap the blood within such that no contamination shall ever occur to the analyzer. |  |  |
|  | The System shall be equipped with a flat panel color display with touch screen, indicating the following parameters and traces:Graphic-drive, on-screen help that consistently reinforces proper procedure while preforming patient testing |  |  |
|  | The System shall be equipped with audio or visual alarms for the following parameters:(a) Ready for use(b) Calibration in progress(c) Test in progress(d) Test completed(e) Error code, if any |  |  |
|  | All cartridges shall have at least 120-day shelf life upon delivery. |  |  |
|  | The printing device shall be a portable and separated thermal printer communicated with the analyzer by infrared radiation (IR) transmission. The printer shall be operated by a rechargeable battery |  |  |
|  | The analyzer shall be able to store not less than 500 patients results and without time limitation if the analyzer has sufficient power supply. |  |  |
|  | The analyzer shall consist of connectivity unit of system, capable of networking to hospital HIS/LIS system |  |  |
|  | This connectivity system shall allow seamless communication of Data between the System and the HIS/LIS. It shall comprise of necessary hardware and software such as POCT interface ports, downloader / dockers, terminal servers and Data Management Workstations for capturing of patient, operator, reagent, quality control and result data uploaded from POCT sites as well as the transmission of these data to the HIS/LIS through the Hospital local area network (LAN). |  |  |
|  | The Successful Tenderer shall be responsible for fixing any bugs in the System within a reasonable time frame by a specialist on site.  |  |  |
|  | The Successful Tenderer shall be responsible for fixing all problems on communication between their offered system and HIS/LIS and guarantee the results shall be uploaded to the patients’ record in HIS/LIS.  |  |  |
|  | The System shall be security options to lock-out unauthorized POCT users and unauthorized reagent lots or specific device unit which fails certain analytical criteria e.g. simulator test. |  |  |
|  | The System shall be suitable for operation at 220 volt (+/- 6%), 50 Hz (+/- 2%). |  |  |
|  | The System shall have a built-in rechargeable battery to support the continuous operation of the System for at least one (1) hour in case of power failure. |  |  |
|  | The System shall be capable of switching back and forth between battery and mains operation in case of power failures. |  |  |
|  | Recharging of the built-in rechargeable battery shall resume automatically when external power becomes available. |  |  |
|  | The System shall be suitable for operation at an ambient temperature of 15°C - 35°C, 70- 95% relative humidity.  |  |  |
|  | Each set of the Analyzer shall be supplied with the following accessories:1. Base station for charging
2. Thermal Printer
 |  |  |
| 2.34 | Sufficient consumables should be provided according to accreditation requirements for user acceptace testing, including 3 levels of QC materials and cartridges.  |  |  |
| 2.35 | The System shall comply the following standards * 1. the latest edition of the safety standard of IEC61010-1 or equivalent
	2. the latest edition of EMC requirement of IEC61010-2-101 or equivalent
	3. the latest edition of the safety standard of IEC61326-2-6 or equivalent.
 |  |  |
| 2.36 | The base station for charging shall comply with IEC 60335-2-29 or equivalent. The base station for charging shall be equipped with over-current protective cut-out device and shall cut off automatically when the battery is fully charged. The base station for charging shall be effectively bonded to earth unless it is double insulated. The base station for charging shall be equipped with over-current protective cutout device. |  |  |
| 2.37 | The accessible parts and accessories of the equipment shall be free of burrs, sharp edges, protrusions and other defects which may cause hazard to pateients and operators. |  |  |
|  |  |  |  |
| **B** | **Implementation Services** |  |  |
|  | The System shall be installed, tested and become ready for use by the timeline specified in Part 4(k) with all costs included within 10 weeks from the date informed by the Hospital. |  |  |
|  | The Successful Supplier shall be responsible for connecting all water inlets, waste outlets and electricity supply to the System and any modification works if required. |  |  |
|  | The Successful Supplier shall be responsible to clear away all packing materials, demolished and unused structural materials to a legal place after delivery/installation of the equipment at no extra charges. |  |  |
|  | The Successful Supplier should note that they will be held responsible for any damage to hospital property or that of the building contractor as may be caused during equipment transportation and installation. The Supplier should take all due measures to protect such property. |  |  |
|  | The Successful Supplier shall be responsible for the make good of ceiling, wall and floor in the installation site after completion of equipment installation.  |  |  |
|  |  |  |  |
| **C** | **Training** |
|  | On-site maintenance and operational training shall be provided at no additional charges for a minimum of two maintenance and operation staff. |  |  |
|  | The supplier shall be responsible to provide session of on-site maintenance training to representatives of CMHHK upon request. The course shall cover at least basic theory of operation, circuit description, trouble-shooting technique, preventive maintenance procedures , calibration and alignment, adjustment. |  |  |
|  | The time-table and commencement dates for the training shall be advised at least one month prior to the commencement of the course. Detailed syllabuses shall be submitted for approval, upon request. The practical part of the training shall coincide with the installation and commissioning of the Goods. |  |  |
|  | Training protocol of operator and content shall be submitted together with the tender return for evaluation Multiple operator training shall be required upon the request of laboratory staff and certificate shall be provided after the training as the reqirement of laboratory accreditation.  |  |  |
|  |  |  |  |
| **D** | **Documentation** |
|  | All photocopies of operation and maintenance manuals shall be properly binded, stamped and certified as true copies of the original by the manufacturer. |  |  |
|  | Any original equipment manufacturer products shall be included, the documents as specified above shall also be provided. |  |  |
|  | At the time of delivery of the equipment, appropriate Set(s) of the manufacturer’s original operation and maintenance manuals in English or in Chinese complete with principle of operations, operation instructions, trouble-shooting techniques, maintenance and calibration procedures, full parts list and full circuit diagrams levels shall be provided with the equipment ordered.  |  |  |
| 4. | The maintenance manuals and checklist for preventive maintenance of the equipment shall be sent to the hospital after order placement but before the equipment delivery for documentation purpose. |  |  |
| 5. | The Successful Tenderer shall provide the authorization letter from manufacturer for providing products, parts and service to end user. The written undertaking shall be signed by a duly authorized representative of the manufacturer and dated no later than the quotation closing date. |  |  |
|  |  |  |  |
| **E** | **Acceptance Tests** |
|  | Safety Test For the purpose of this contract the Goods shall be subject to a safety test after delivery and installation. Such test is to be carried out by by the Contractor with the witness of representative of CMHHK.. The safety test will normally be conducted within 6 to 8 weeks after delivery and installation of the Goods. The date of completion by the Authority based upon the satisfactory result of such safety test. |  |  |
|  | Functional TestFor the purpose of this Contract the Goods shall be subject to a functional test for its conformance with the operational and reliability requirements to the satisfaction of the user. The successful tenderer shall provide all reagents and consumables for the evaluation. In the event that the equipment fails to conform to the above stated requirements, the successful tenderer is required to carry out appropriate remedial measures and/or any rectification works, including replacement of the entire equipment, where deemed necessary. The date of acceptance of the Goods shall be determined by the Hospital based upon the satisfactory completion of such functional test. |  |  |
|  |  |  |  |
| **F** | **Indicative Warranty Service** |
|  | The potential supplier shall guarantee the equipment or any part thereof for a period of at least 12 months commencing from the date of acceptance of the equipment. The potential supplier shall also replace faulty parts and provide both schedule and breakdown maintenance service by qualified maintenance personnel. In case of replacement of parts, they will be free of charge. |  |  |
|  | The potential supplier shall submit as an essential part of the offer a yearly maintenance schedule during the warranty period indicating the number of preventive maintenance services required for ensuring a satisfactory performance of the equipment offered. Document, form, operation/service manual and/or manufacturer’s confirmation shall be submitted. If such information is not available, at least two times of preventive maintenance services shall be provided annually. The maintenance services shall be carried out in accordance with the maintenance procedures as described in the relevant equipment services manuals. |  |  |
|  | The preventive maintenance work shall be carried out as follows with no additional charge:Normal working hours (09:00 – 18:00 hours Monday to Friday, excluding public holidays and 09:00 - 13:00 Saturday, excluding Public Holiday). |  |  |
|  | The potential supplier shall be responsible to make good to the satisfaction of CMHHK Operator, any defects on the equipment due to improper workmanship, faulty design or component failure which may arise within the warranty period of the equipment. |  |  |
|  | Upon notification by the CMHHK Operator of a defect (departure from performance specifications) in the operation of the equipment of part thereof, the supplier shall perform the corrective maintenance within 48 hours upon request from the CMHHK Operator. This service shall include all necessary repairs, adjustment and replacement of parts to restore the equipment to its normal operational conditions in a time of no more than 3 working days. If such work being maintenance are not completed at the end of particular normal working period, subject to the CMHHK Operator’s agreement, the maintenance work will either be completed on next working day, or arrangement will be made for the supplier to carry on working until the particular maintenance task is completed. |  |  |
|  | Upon completion of the corrective maintenance works, the potential supplier shall submit a report on the equipment breakdown investigation result and corrective action taken. |  |  |
|  |  |  |  |
| **G** | **Indicative Maintenance Service** |
|  | The potential supplier shall quote the charge for annual maintenance services after the warranty period within the serviceable life of the proposed Goods. |  |  |
|  | The potential supplier shall submit a price list of all spare parts of the Goods chargeable to the CMHHK Operator. For spare parts not covered by the submitted prices, the potential supplier must submit a quotation to the CMHHK Operator for consideration every time when spares are required. |  |  |
|  | The potential supplier shall deploy properly trained service personnel to carry out the maintenance services and shall ensure that all necessary precautions for their safety are taken. |  |  |
|  | The potential supplier shall provide free of additional charge corrective maintenance service for providing immediate repair service for the goods and related equipment in normal working hours. |  |  |
|  | The maintenance services shall be carried out in accordance with the maintenance procedures as described in the relevant equipment services manuals. |  |  |
|  | Upon notification by the CMHHK Operator of a defect (departure from performance specifications) in the operation of the equipment of part thereof, the potential supplier shall perform the corrective maintenance within 48 hours upon request from the CMHHK Operator. This service shall include all necessary repairs, adjustment and replacement of parts to restore the equipment to its normal operational conditions in a time of no more than 3 working days. If such work is not completed at the end of particular normal working period, subject to the user’s agreement, the maintenance work will either be completed on next working day, or arrangement will be made for the supplier to carry on working until the particular maintenance task is completed.  |  |  |
|  | Upon completion of the corrective maintenance works, the supplier shall submit a report on the equipment breakdown investigation result and corrective action taken. |  |  |
|  |  |  |  |
| **H** | **Spare Parts** |  |  |
|  | The supplier shall guarantee the availability of maintenance spare parts for the anticipated life of the System.  Sufficient spare parts shall be held by the successful supplier to cater for the maintenance during the warranty period. |  |  |
|  | The suppliers, in their tender submission, shall provide a comprehensive list of recommended spare parts with unit prices valid for at least one (1) year after expiry of warranty. |  |  |

**Part 4 – Implementation Plan**

*(Note to Suppliers: Please provide the estimated time periods required for the completion of the following tasks, counting from the date of issue an order (“Order Date”). Both the start and end date of the Order Date is referenced as* ***Month 0****. The System should be* ***Ready for Use in the last month of the Implementation Plan.****)*

|  |  |
| --- | --- |
| **Tasks of the Implementation Plan** | **Estimated Time Period for** **Performing the Tasks**(The Order Date is set as Month **0**) |
| **Start** (Month) | **End** (Month) |
|  | Order Date *(i.e. the date of order placed by the Government, if any)*  | **0** | **0** |
|  | Submission of Site Preparation Information (if applicable) |  |  |
|  | Design of the System (if applicable) |  |  |
|  | Delivery of the System  |  |  |
|  | Installation of the System |  |  |
|  | Implementation Services (*Please refer to* ***section B in Part 3*** *for details*) |  |  |
|  | Delivery of Documentation (*Please refer to* ***section D in Part 3*** *for details*) |  |  |
|  | Training (*Please refer to* ***section C in Part 3*** *for Details*) |  |  |
|  | Acceptance Tests |  |  |
|  | Any other tasks considered necessary by your company *(Please provide details, use separate sheet if space is insufficient)*: |  |  |
|  | System Ready for Use *(i.e. the date when the System has passed all acceptance tests and accepted by the Government)*  | **0** |  |

**Part 5 – Information on Compliance with International, National and other Recognised Standards** **or Certifications (if applicable)**

(*Note to Suppliers: Please indicate in the box below whether the proposed Analyzer, Point-Of-Care, Renal Function Test Device can meet with the standards stated in Column I* ***by inserting a tick in an appropriate box under Column III****. If your proposed Analyzer, Point-Of-Care, Renal Function Test Device does not meet the standards stated in Column I, please indicate the equivalent standards met by your proposed Analyzer, Point-Of-Care, Renal Function Test Device in Column IV. In any case,* ***please attach copies of relevant valid certificates to prove compliance with such standards****.*)

|  |  |  |  |
| --- | --- | --- | --- |
| **Column I** | **Column II** | **Column III** | **Column IV** |
| International, National and other Recognised Standards or Certifications | Requirements  | Comply with the Standard in Column I? | Comply with the following equivalent standard (*If “****No****” in Column III*) |
| Yes | No |
| The latest edition of the safety standard of IEC61010-1 or equivalent  | As per the requirements stated in clause 2.35 |  |  |  |
| The latest edition of EMC requirement of IEC61010-2-101 or equivalent  | As per the requirements stated in clause 2.35 |  |  |  |
| The latest edition of the safety standard of IEC61326-2-6 or equivalent | As per the requirements stated in clause 2.35 |  |  |  |
| The base station for charging shall comply with IEC 60335-2-29 or equivalent | As per the requirements stated in clause 2.36 |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
| Compliance with other international, national and recognised standard(s) or certification(s) in addition to the above (*please specify*) |
|  |  |  |  |  |

**Part 6 – Information on Licencing, Marketing Authorization and MDACS Listing (if applicable)**

(*Note to Suppliers: Please advise whether your company and the proposed System have the following licence, marketing authorization and Medical Device Administrative Control System (“MDACS”) listing. If affirmative, please provide copies of relevant licences, confirmation and certificates for our reference.)*

| Question | Licensing/Certification/Listing Information of the System |  *(Please tick in the appropriate box)* |
| --- | --- | --- |
| #Yes | No |
| 1 | Does your company have valid licence(s) to sell, deal with, possess and use irradiating apparatus in Hong Kong issued under the Radiation Ordinance (Chapter 303 of the Laws of Hong Kong) (“IA Licence”)? |  |  |
| 2 | Has the proposed System been listed in a valid IA Licence? |  |  |
| 3 | Dose the proposed System have marketing authorization of Food and Drug Administration (FDA) of the United States? |  |  |
| 4 | If the proposed System has marketing authorization of FDA, please specify below the type of marketing authorization (i.e. approval, clearance or exemption). \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |
| 5 | Does the proposed System have marketing authorization of the European Union (EU) for affixing of CE marking on the product? |  |  |
| 6 | If the proposed System has marketing authorization of EU, please state the type of supporting document (\*delete which is not applicable).* + - * 1. \*Declaration of conformity by the manufacturer; or
				2. \*Certificate of conformity issued by a notified body.
 |  |  |
| 7 | Does the proposed System have marketing authorization in country/region other than United States and EU? Please specify below if your answer is “Yes”.Country / Region : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |
| 8 | Has your proposed System been listed in the MDACS of the Department of Health?  |  |  |
| 9 | What class of medical device is your proposed System (if applicable)?1. EU : Class \_\_\_\_\_\_
2. United States : Class \_\_\_\_\_\_
3. Other country/region (please specify below):
* Country/Region \_\_\_\_\_\_\_\_\_
* Class \_\_\_\_\_\_\_\_\_
 |  |  |

#Please provide a copy of the licence/confirmation/certificate for reference.

**Part 7 – Indicative Price Information**

(*Note* *to Suppliers: The price information provided in this Part 7 is for Government’s consideration only and shall not constitute any commitment on the part of the Government or your company. Nevertheless, please provide the information as accurate as possible.*)

**(a) Indicative Price Information for the System**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Item** | **Description** | **Estimated****Quantity** | **Unit Price** | **Estimated Goods Price** |
| **One-time Unit Price(HK$)** | **Estimated Goods Price for the Item specified opposite****(HK$)** |
|  |  | **(a)** | **(b)** | **(c) = (a) x (b)** |
| 1 | Supply, delivery, installation, testing and commissioning of the System and related accessories, as more particularly specified in **section A1.1 in Part 3**, including the provision of a minimum 12-months warranty period. | 3 set |  | ***(Please also provide breakdown cost for key components of the System, if any)*** |
| 2 | Provision of implementation services as detailed in **section B in Part 3** | 1 lot |  |  |
| 3 | Provision of training services as detailed in **section C in Part 3**  | 2 courses |  |  |
| 4 | Documentation as detailed in **section D in Part 3** | 1 lot |  |  |
| 5 | Other (please specify) | (please specify) |  |  |
| **Total One-time Charge**(i.e. Sum of Estimated Goods Prices of Item 1- 5) |  |

**(b) Indicative Price Information for Selected Desirable Features (if applicable)**

|  |  |  |
| --- | --- | --- |
| **Aspect** | **Description of Selected Desirable Features** | **Any Additional Charge to Total One-time Charge as Specified in Part 7(a)**(Please tick whichever is applicable)  |
| 1 | Not Applicable | □ No additional charge□ Require additional charge: HK$ \_\_\_\_\_\_\_\_\_ |

**Part 8 – Indicative Maintenance Charges and Spare Parts Price**

(Notes to Suppliers for completion of Part 8)

1. *Pursant to item 1 of Part 7(a) above, the proposed System shall have a warranty period of not less than 12 months. The indicative warranty service requirements are stipulated in* ***section F in Part 3****, which are subject to changes at the sole discretion of the Government.*
2. *Indicative maintenance service requirements after the free warranty period are stipulated in* ***section G in Part 3****, which are subject to changes at the sole discretion of the Government*
3. *It is expected that the maintenance services shall be comprehensive, all inclusive and shall cover all parts, components, labour and software support services. If your company considers that any components of the System may not be covered by the maintenance services (****saving that the labour shall always be covered by the maintenance services****) and may need to be charged separately, please indicate replacement costs of these components and their replacement frequency.*
4. *The annual maintenance charge within the serviceable life of the proposed System* ***is adjustable in accordance with the consumer price index (B) upon the expiry of each 12-months period of maintenance service****.*
5. **Indicative Maintenance Prices of the Proposed System**

| **Year** | **Annual Maintenance Charge****(HK$ per annum)** |
| --- | --- |
| First 12-months period of maintenance service after the end of warranty period |  |

1. **Indicative Replacement Prices of System’s Components not covered by the Maintenance Services (if applicable) (***Leave the following table blank if not applicable***)**

(*Note to Suppliers:* ***The labor costs for replacement of these components shall always be covered by the maintenance charges for the provision of the maintenance services*** *regardless whether the prices for the supply of these components are covered by the maintenance services or not.)*

|  |  |  |  |
| --- | --- | --- | --- |
| Item | Name of Items | Indicative Replacement Price (HK$/no.) | Indicative Replacement Frequency (*e.g. once every 3 years*) |
| 1 |  |  |  |
| 2 |  |  |  |
| 3 |  |  |  |

1. **Indicative overtime charges for provision of maintenance services after office hours (if applicable)**

(*Office hours mean 9 am to 6 pm from Monday to Friday excluding public holidays*)

|  |  |  |
| --- | --- | --- |
| (a) | Rates of overtime charges for maintenance service outside the office hours | HK$ per hour |
| (b) | Minimum service hour(s) per call |  service hour(s) per call |

1. **Indicative Prices for Replacement of Other Spare Parts (if applicable)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Item | Name of Items | Price (HK$/no.) | Indicative Replacement Frequency (*e.g. once every 3 years*) | Expected time for delivery (weeks) |
| 1 |  |  |  |  |
| 2 |  |  |  |  |
| 3 |  |  |  |  |
| 4 |  |  |  |  |
| 5 |  |  |  |  |
| 6 |  |  |  |  |

1. **Indicative Price for Annual Support Services of Software (if applicable)**

(*Note to Suppliers:* Please provide below annual charge for support services of the System’s software during the serviceable life of the System for the CMHHK Operator’s consideration. *The support services should include but not limited to:*

1. *provision and renewal of software toolkits, access codes, passwords, software keys and hardware keys, etc. necessary for all kinds of adjustments, in-depth diagnosis and trouble shooting of the System; and*
2. *version upgrade of the software.)*

|  |  |
| --- | --- |
|  | (a) Free of charge during serviceable life  |
|  |  |
|  | (b) Yearly cost at $\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Part 9 – Supplementary Information**

1. Number of proposed System Already Installed (leave blank if information is not available)

In Hong Kong : \_\_\_\_\_\_\_\_\_\_ sets

Globally : \_\_\_\_\_\_\_\_\_\_ sets

1. Year of Launch of the Proposed System (leave blank if information is not available)

My/our proposed System was first launched in the market in Year \_\_\_\_\_\_\_\_\_\_\_\_\_

1. Pre-Installation Requirements of the Proposed System (if any)

*(Pre-installation requirements may include any preparation work and provisions that are necessary for the installation of the System, such as the requirements of ceiling mount support, power supply requirements, etc.)*

**END**