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

**Request for Market Information (“RFI”) for
Supply and Installation of Sterilizing Unit (Hydrogen Peroxide Gas)**

**for the Chinese Medicine Hospital (“CMH”)**

**(CMHPO Ref. : HHB/H/24/17/3/4/4)**

To : Project Director (CMHPO)

 (Attn. Sandra Leung)

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

Your ref: (1) in L/M to HHB/H/24/17/3/4/4

In response to the RFI of the CMH, 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 10 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)

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*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 and installation of Sterilizing Unit (Hydrogen Peroxide Gas) (hereinafter refers as the “**Goods**”) for the Chinese Medicine Hospital (“**opCMH**”) located at Pak Shing Kok in Tseung Kwan O. The CMHPO therefore wishes to collect market information on the Sterilizing Unit (Hydrogen Peroxide Gas).

1. Background of the CMH 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 CMH. The 2017 Policy Address stated that the Government decided to finance the construction of the CMH and identify by way of tender a suitable non-profit-making organisation (“NPMO”) to operate the CMH. CMH will be owned by the Government and the selected NPMO will operate the CMH. The CMH 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 CMH 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 CMH covers inpatient, day-patient, outpatient and community outreach services.

To take forward the planning and development of the project on CMH, 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 CMH 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 CMH. The CMH 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 CMH 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 model of Sterilizing Unit (Hydrogen Peroxide Gas) that may meet the requirements of the Goods stated in this Proforma, **please complete and return, together with relevant supporting documents, one set of Proforma for each different model of** Sterilizing Unit (Hydrogen Peroxide Gas).

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

|  |  |
| --- | --- |
| 1. Place of origin
 |  |
| 1. Name of manufacturer
 |  |
| 1. Address of the manufacturer’s factory or plant (“Manufacturing Plant”)
 |  |
| 1. Product name of the Goods
 |  |
| 1. Model number/ name/ version number of the Goods
 |  |
| 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 Goods

(*Please refer to section F in Part 3 for details of the warranty service requirements*) | \_\_\_\_\_\_\_\_\_\_\_\_ months from Acceptance of the Goods(*Should not be less than 12 months*) |
| 1. Expected serviceable life (*Please specify any components of the Goods that cannot meet the serviceable life*)
 | The Goods 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 “****Goods****” 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 Goods “****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 Goods 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 Goods 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** |
|  | **Technical Requirements** |
|  | **Goods to be Supplied** |
|  | One set of integrated low temperature vaporized hydrogen peroxide plasma sterilizing unit as stipulated in these Technical Specifications (hereinafter refers as “Sterilizing Unit” or “Goods”). |  |  |
|  | **Intended Use of the Goods** |
|  | The Goods shall use low temperature gas plasma (vapourized hydrogen peroxide) to sterilize medical instruments without leaving toxic residues.  |  |  |
|  | The Goods shall perform the following three functions: |  |  |
|  | 1. Process device with stainless steel lumen with internal diameter ≥ 0.7mm and ≤500mm in length.
 |  |  |
|  | 1. Process device with polyethylene or similar material lumen with internal diameter ≥ 1mm and ≤ 1000mm in length.
 |  |  |
|  | 1. Process flexible endoscope with lumen with internal diameter ≥ 1mm and ≤ 850mm in length.
 |  |  |
|  | **Functional and Performance Requirements of the Goods** |  |
|  | The Goods shall be an integrated system. |  |  |
|  | The Goods shall allow choice of various networking capability to provide real time sterilization information for tracking and tracing capability. |  |  |
|  | The Goods shall have automated rapid biological indicator (BI) system to provide result in less than 15 minutes for fast turnaround of instruments; interface to system network and no manual recording is needed. |  |  |
|  | The Goods shall be connected to workstation. |  |  |
|  | **Chamber specifications** |
|  | The chamber shall be rectangular in shape. |  |  |
|  | The chamber volume shall be ≥ 150 litre. |  |  |
|  | The chamber shall be divided into two shelves, each shelf shall withstand ≥ 25kg loading. |  |  |
|  | The dimensions of the two-tier shelf design shall be ≥ 440mm (W) and 640mm (D). |  |  |
|  | Both shelves shall be removable.  |  |  |
|  | **Cycle temperature** |
|  | The cycle temperature range of the Goods shall be 47 °C to 56 °C throughout the sterilization cycle. |  |  |
|  | The highest cycle temperature shall not be higher than 56 °C, to avoid inducing damage to heat sensitive surgical instrument(s) during the sterilization cycle. |  |  |
|  | **Door specifications** |
|  | The Goods shall be a two-door design with automatic door design and sliding door function which can be operated either by touch panel or foot pedal. |  |  |
|  | Safety mechanism shall be applied to the automatic door such that it would stop immediately if obstruction be encountered. |  |  |
|  | The pass-through door design shall be disabled any time to become a single-door mode operation when needed. |  |  |
|  | **Operation environment** |
|  | The optimal operating temperature of the Goods shall be between 18 °C to 35 °C.  |  |  |
|  | The optimal operating relative humidity of the Goods shall be 10% to 85% (non-condensing). |  |  |
|  | The heat generation of the Goods shall be 4,500 +/- 10% BTU/ hour when idled with maximum not exceeding 6,200 BTU/ hour.  |  |  |
|  | **Operation and navigation** |
|  | The Goods shall be equipped with a touch screen LCD monitor to display system and cycle status which allows the entry of load information or configuration of the system. |  |  |
|  | The LCD monitor shall be 300mm or larger to facilitate daily operation. |  |  |
|  | The monitor shall adopt GUI to show proper load placement for selected cycle and touch screen technology for cycle navigation. |  |  |
|  | The sterilant shall be in sealed cassette design that provide coded information which reflect cassette lot/batch number, manufacturing and expiry days and cell status in both the sterilizer and the connection network. |  |  |
|  | There shall be a leaking indicator outside wrappers or package to alert customers on chemical leaking. |  |  |
|  | Used cassettes shall automatically drop into the collection box when used up and users need not remove any used cassettes/cartridge. |  |  |
|  | There shall be a cassette disposal box to collect used cassettes. Used disposal chemicals to be disposed in line with hospital policy. |  |  |
|  | **Tracking and tracing** |
|  | The Goods shall allow tracking and tracing of full electronic cycle data (including but not limited to critical parameters such as H2O2 concentration, temperature, pressure, plasma power, cycle time, cycle number), cycle history and system analysis. |  |  |
|  | The Goods shall allow electronic storage for up to 200 cycle history records, and be equipped with a built-in printer for manual record keeping. |  |  |
|  | The cycle data of the Goods, history and system analysis should be tracked and traced. |  |  |
|  | **Sterilization specifications** |  |  |
|  | The sterilization process of terminal sterilization using double kill cycle, a sterility assurance level of 10-6 shall be achieved. |  |  |
|  | The sterilization process shall include a total of two injections and identical plasma phases for different types of cycle programs to enhance standardized sterilant condition between cycles. |  |  |
|  | The system shall be equipped with on-board sensors, biological indicators and chemical indicators and optional independent monitoring system to monitor the critical parameters. |  |  |
|  | The sterilization process shall comply with the clauses from 10.4.1 to 10.4.7 below. |  |  |
|  | An automatic, pre-cycle diagnostic and load conditioning process that takes less than 7 minutes to facilitate moisture detection and removal and to ensure optimal package and instrument conditions for sterilization. |  |  |
|  | Deep vacuum shall be drawn into the chamber after closing of chamber door. |  |  |
|  | A 58-59.6% aqueous H2O2 shall be injected, the H2O2 in the delivery system shall be condensed and concentrated and then be diffused into the chamber. |  |  |
|  | A low frequency electric current shall be delivered through the chamber electrode, forming a low temperature gas plasma in the chamber. |  |  |
|  | The Goods shall have a plasma stage to decompose the H2O2 vapour back to safe end-products such as water vapour and oxygen.  |  |  |
|  | The combined use of H2O2 and plasma is proven to safely sterilize medical instruments without leaving toxic residues. |  |  |
|  | The Goods shall protect healthcare professionals from H2O2 exposure all the time in the working environment. The H2O2 emissions shall meet both the OSHA 1ppm (8 hour) time-weighted average and ACGIH short-term peak exposure at below 5ppm. Evidential documents shall be provided to support this clause, upon request.  |  |  |
|  | The system shall allow selection of cycles for sterilization of different medical devices. |  |  |
|  | Sterilization shall be achieved in less than or equal to 25 minutes for robotic devices, rigid endoscopes, rechargeable batteries, eye instruments and ultrasound probes instruments that are without lumen.  |  |  |
|  | Sterilization shall be achieved in less than or equal 45 minutes for selected flexible endoscopes such as bronchoscopes, hysterocopes, cystoscopes and choledochoscopes from commonly used brands of local hospitals.  |  |  |
|  | Sterilization shall be achieved in less than or equal to 50 minutes for most medical devices with lumen, such as rigid endoscopes, cameras, light cords, rechargeable batteries and ultrasound probes.  |  |  |
|  | Sterilization shall be achieved in less than or equal to 60 minutes for most common flexible endoscopes such as bronchoscopes, hysterocopes, cystoscopes and choledochoscopes from commonly used brands of local hospitals. |  |  |
|  | **Sterilization process and control** |
|  | The sterilizer shall have a control system to measure the critical parameter including temperature, pressure, hydrogen peroxide concentration, plasma power and time. The system shall abort cycle beyond ranges with alarm and indication. |  |  |
|  | The sterilizer shall have seven temperature sensors in the system with locations on: vaporizer, condenser, doors; and chamber front, middle and rear end. |  |  |
|  | The sterilizer shall have three pressure transducers and an atmospheric pressure switch. The control system interacts with these components during chamber evacuation, pressure monitoring and venting to atmosphere. |  |  |
|  | The sterilizer shall have the ultraviolet lamp assembly sits at the top front of the chamber and deliver UV light across the chamber to the detector mounted at the bottom of the chamber. |  |  |
|  | A photodiode detector measures the amount of light coming from the lamp, before and during hydrogen peroxide transfer to the chamber, allowing a calculation of the hydrogen peroxide concentration. |  |  |
|  | The sterilizer shall have monitoring and control system controls the plasma power during plasma process. |  |  |
|  | The sterilizer shall monitor and control the time of different steps in the process. An internal timer measures process steps duration and the computer uses time inputs to control the various devices in the process sequence. |  |  |
|  | In addition to sterilizer main controller, optional IMS shall be available to provide another set of cycle data (temperature, pressure, plasma power) for the purpose of system verification and /or parametric release. |  |  |
|  | The sterilizer shall remind user to input biological indicator before cycle start. |  |  |
|  | The system shall verify and record the details of the biological indicator such as log numbers and expiry dates. |  |  |
|  | The system shall be able to automatically backup cycle data and BI incubation data to a storage device such as USB. |  |  |
|  | **Weight and Dimensions** |
|  | The total weight of the Goods shall not exceed 350 kg. |  |  |
|  | The external dimensions shall be: 770mm (W) ± 10%, 1800mm (H) ± 10% and 1090mm (D) ± 10%.  |  |  |
|  | The internal dimensions shall be: 500mm (W) ± 10%, 400mm (H) ± 10% and 730mm (D) ± 10%. |  |  |
|  | The installation of one unit of the Goods with service clearance area shall not exceed the total dimension of 2,400 mm +/- 1% (W) x 3,000 mm +/- 1% (D) x 2,000mm +/- 1% (H). |  |  |
|  | The workstation area for BI incubation and Data networking shall not exceed 500 mm +/- 1% (W) x 500 mm +/- 1% (H) x 500mm +/- 1% (D). |  |  |
|  | **Other requirements** |
|  | The Goods shall be supplied with a cassette disposal box which can hold depleted sterilant cassettes. |  |  |
|  | The Goods shall have an I/O panel which provides external communication connection from the system control enclosure including, but not limited to USB port. |  |  |
|  | The Goods shall have a storage of cycle data which can be viewed on screen or downloaded to other computers. |  |  |
|  | The main controller’s cycle data shall include all critical parameters at one-second interval. |  |  |
|  | The Goods shall have cycle data automatically tracked and traced via computer systems. |  |  |
|  | The Goods shall allow language selection including Chinese and English  |  |  |
|  | The Goods shall be supplied with an integrated reader for the rapid BI. |  |  |
|  | The Goods shall be supplied with FDA cleared instruments container trays, mats and holders. |  |  |
|  | The Goods shall accept multiple choice of validated instrument trays to house various sizes of endoscopes and ultrasonic probes. |  |  |
|  | **Safety and Product Standards** |
|  | The Goods shall comply with the latest editions of the following international standards (or equivalent): |  |  |
|  | 1. ISO 14937:2009 Sterilizing of health care products or equivalent;
 |  |  |
|  | 1. CAN/CSA-C22.2 No. 61010-1/R: 2009;: Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use;
 |  |  |
|  | 1. UL 61010-1/R: 2008;: Standard for Safety for Electrical Equipment for Laboratory Use;
 |  |  |
|  | 1. EN 61010-1: 2001; Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use;
 |  |  |
|  | 1. EN 55011, Group I Class A limits, based on CISPR 11:2009, Group I Class A limits (subset of EN 60601-1-2);
 |  |  |
|  | 1. RF emissions CISPR 11 , Group 1;
 |  |  |
|  | 1. RF emissions CISPR 11 , Class A;
 |  |  |
|  | 1. Harmonic emissions IEC 61000-3-2, Class A;
 |  |  |
|  | 1. Voltage fluctuations / flicker emissions IEC 61000-3-3;
 |  |  |
|  | 1. IEC/EN 61010-2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials, 1st Ed., 2005;
 |  |  |
| 1. IEC 61326-1: Electrical equipment for measurement, control and laboratory use – EMC requirement
 |  |  |
|  | The Goods shall be approved by a national regulatory authority under stringent regulatory processes as evidenced by: |  |  |
|  | 1. valid approval or clearance or exemption by the United States Food and Drug Administration (FDA); or
 |  |  |
|  | 1. Conformité Européenne/European Conformity (CE) marking; or
 |  |  |
|  | 1. appropriate national regulatory clearance from other members of the International Medical Device Regulators Forum (IMDRF).
 |  |  |
| 14.3 | Other Safety Requirement: |  |  |
|  | 1. The Goods shall be effectively bonded to earth unless it is double insulated.
 |  |  |
|  | 1. The Goods shall be equipped with an over-current protective cutout device.
 |  |  |
|  | 1. All components of the equipment shall be free of burrs, sharp edges, protrusions and other defects which may cause hazard to the patient or staff. All surfaces and edges shall be smooth and non-abrasive.
 |  |  |
|  | **Quality Management System**  |
|  | The Manufacturer shall have valid ISO 13485:2016 (or the latest version) certification or equivalent for the scope relevant to the Goods. |  |  |
|  | The Manufacturer shall have valid ISO 14937:2009 (or the latest version) certification or equivalent for the scope relevant to the Goods. |  |  |
|  | **Electricity Supply and Environmental Conditions**  |  |  |
|  | The Goods shall be designed for operation on local electricity supply of a 30 Amp, 380 Volt +/- 6%, 50Hz +/-2%, 3-phase power supply. |  |  |
|  | **Implementation Services** |
|  |  **Delivery Requirement** |
|  | The potential supplier shall provide the conditions of delivery, including but not limited to packing and necessary environmental requirements for the CMH Operator’s consideration. |  |  |
|  | The potential supplier shall arrange insurance coverage they think right and appropriate to cover damages to the equipment during the period of delivery, storage, installation, testing and commissioning. The potential supplier shall provide their own temporary protection for their works before hand-over of the works to the CMH. |  |  |
|  | The potential 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 his own cost. |  |  |
|  | Full functional tests for demonstration of compliance of the Goods with operational and reliability requirements shall be provided by the potential supplier to the satisfaction of the CMH Operator. |  |  |
|  | **Installation of the Goods** |
|  | Coordination with the Design and Build Contractor and other Government contractors for the installation of the Goods (please refer to Appendix 1 for the composite drawings). |  |  |
|  | Inclusion of all installation work which shall be carried out by suitably qualified persons including without limitation registered electrical worker(s) with valid registration under relevant legislation.  |  |  |
|  | The potential supplier shall be responsible for installation including electrical cabling / wiring works and other building service provision, the supplier shall include the costing of the installation in their quotation or declare to request user/ requisite department to arrange with the relevant department of such installation work. The building service installations provided by the supplier shall comply with requirements of the General Specification for Building Service Installations in Government Buildings of the HKSAR (and any corrigendum) issued by the Architectural Services Department. |  |  |
| 2.3.1 | The successful tenderer shall be fully responsible for the builder’s works in relation to the installation of the equipment, including but not limited to wall opening, sealing of the gap between the equipment and wall opening, etc. The builder’s works provided by the successful tenderer shall comply with requirements of the General Specification for Building (and any corrigendum) issued by the Architectural Services Department. |  |  |
|  | The price quoted shall include local delivery, installation, on-site acceptance testing, commissioning and training.  |  |  |
|  | The potential supplier shall provide the conditions of delivery, including but not limited to packing and necessary environmental requirements for the CMH’s consideration. |  |  |
|  | The potential supplier shall arrange insurance coverage they think right and appropriate to cover damages to the equipment during the period of delivery, storage, installation, testing and commissioning. The supplier shall provide their own temporary protection for their works before hand-over of the works to CMH. |  |  |
|  | The potential 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 his own cost. |  |  |
|  | The installation shall be in compliance with the relevant requirements of the latest edition of “Electrical Products (Safety) Regulation” under Electricity Ordinance, Cap. 406 and “Code of Practice for the Electricity (Wiring) Regulations” enforced by concerned parties (e.g. EMSD). |  |  |
|  | **IT Requirement** |  |  |
|  | The potential supplier shall be responsible for the security of the system by following the Furniture and Equipment IT Security Guidelines for CMH (please refer to Appendix 2). |  |  |
|  | The potential supplier shall work with the contractor of CMH IT infrastructure services to ensure the proper hosting, installation and configuration of the system as described in CMH IT Infrastructure Services Specifications for Furniture and Equipment (please refer to Appendix 3). |  |  |
|  | **Training** |
|  | **Local Operation and Service Training** |  |  |
|  | On-site operational training shall be provided at no additional charges for a minimum of two operation staff. |  |  |
|  | 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. |  |  |
|  | The supplier shall be responsible to provide at least One (1) session of on-site maintenance training to representatives of CMH upon request. The course shall cover basic theory of operation, circuit description, trouble-shooting technique, calibration and alignment, adjustment, etc. |  |  |
|  | **Documentation** |
|  | **Operation and Service Manual** |  |  |
|  | Three sets each of (1 original and 2 copies) English operation manuals and service manuals with principles of operation, operation instructions, preventive maintenance procedures, trouble-shooting technique, alignment and calibration of the equipment, full parts list and all circuit diagrams shall be provided with the Goods before or at the time with the delivery. |  |  |
|  | The supplier shall provide all necessary passcodes or passwords for enabling the Government’s representatives to carry out servicing and maintenance for the Goods. If service cards or dongles are required for enabling the Government’s representatives to carry out servicing and maintenance, two (2) sets of such service cards or dongles shall be provided to the Government within one month after the commencement of the warranty period. |  |  |
|  | **Acceptance Tests** |
|  | The Goods shall be tested for acceptance at site by the CMH Operator and/or the potential supplier. The test shall include checking on materials used, safety device/features, structure strength, functional test and performance. |  |  |
|  | The potential supplier shall provide all testing instruments to conduct site acceptance tests. All testing instruments to be used for the acceptance test shall be calibrated and copies of calibration certificates or other supporting documents shall be forwarded to the CMH Operator for records. |  |  |
|  | Full functional tests for demonstration of compliance of the equipment with operational and reliability requirements shall be provided by the potential supplier to the satisfaction of the CMH Operator. In the event that the Goods fails to conform to the above stated requirements, the potential supplier is required to carry out appropriate remedial measures and/or any rectification works, including replacement of the entire equipment, where deemed necessary. |  |  |
|  | The supplier shall submit the acceptance test schedule, procedures, forms and testing method to the end-user for prior approval before the tests. |  |  |
|  | **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 hours0900 - 1800 hours Monday to Friday, excluding public holidays |  |  |
|  | The potential supplier shall be responsible to make good to the satisfaction of CMH 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 CMH 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 CMH 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 CMH 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. |  |  |
|  | **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 CMH Operator. For spare parts not covered by the submitted prices, the potential supplier must submit a quotation to the CMH 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 CMH 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 CMH 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. |  |  |
|  | **Spare Parts** |
|  | The supplier shall guarantee the availability of maintenance spare parts for the anticipated life of the Goods.  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 Goods 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 Goods (if applicable) |  |  |
|  | Delivery of the Goods  |  |  |
|  | Installation of the Goods |  |  |
|  | 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)*: |  |  |
|  | Goods Ready for Use *(i.e. the date when the Goods 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 Sterilizing Unit (Hydrogen Peroxide Gas) can meet with the standards stated in Column I* ***by inserting a tick in an appropriate box under Column III****. If your proposed Sterlizing Unit (Hydrogen Peroxide Gas) does not meet the standards stated in Column I, please indicate the equivalent standards met by your proposed Sterlizing Unit (Hydrogen Peroxide Gas)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 |
| ISO 14937:2009 | Sterilizing of health care products |  |  |  |
| CAN/CSA-C22.2 No. 61010-1/R: 2009 | Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use |  |  |  |
| UL 61010-1/R: 2008 | Standard for Safety for Electrical Equipment for Laboratory Use |  |  |  |
| EN 61010-1: 2001 | Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use |  |  |  |
| EN 55011 | Group I Class A limits, based on CISPR 11:2009, Group I Class A limits (subset of EN 60601-1-2) |  |  |  |
| CISPR 11 | RF emissions CISPR 11, Group 1 |  |  |  |
| CISPR 11 | RF emissions CISPR 11 , Class A |  |  |  |
| IEC 61000-3-2 | Harmonic emissions IEC 61000-3-2, Class A; |  |  |  |
| IEC 61000-3-3 | Voltage fluctuations/ flicker emissions IEC 61000-3-3; |  |  |  |
| IEC/EN 61010-2-040 | Particular requirements for sterilizers and washer-disinfectors used to treat medical materials, 1st Ed., 2005 |  |  |  |
| IEC 61326-1  | Electrical equipment for measurement, control and laboratory use – EMC requirement |  |  |  |
| 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 Goods 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 Goods |  *(Please tick in the appropriate box)* |
| --- | --- | --- |
| #Yes | No |
| 1 | Dose the proposed Goods have marketing authorization of Food and Drug Administration (FDA) of the United States? |  |  |
| 2 | If the proposed Goods have marketing authorization of FDA, please specify below the type of marketing authorization (i.e. approval, clearance or exemption).\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |
| 3 | Does the proposed Goods have marketing authorization of the European Union (EU) for affixing of CE marking on the product? |  |  |
| 4 | If the proposed Goods have 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.
 |  |  |
| 5 | Does the proposed Goods have marketing authorization in country/region other than United States and EU? Please specify below if your answer is “Yes”.Country / Region : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |
| 6 | Have your proposed Goods been listed in the MDACS of the Department of Health?  |  |  |
| 7 | What class of medical device is your proposed Goods (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 Goods**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **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 Goods as more particularly specified in **section A in Part 3**, including the provision of a minimum 12-months warranty period. | 1 set |  | ***(Please also provide breakdown cost for key components of the Goods, if any)*** |
| 2 | Provision of implementation services as detailed in **section B in Part 3** | 1 job |  |  |
| 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) |  |

Note: \* The Total One-time Charge shall include one-year of warranty period.

**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 Goods 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 Goods 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 Goods* ***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 Goods**

| **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 Goods’ 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 Goods’ software during the serviceable life of the Goods for the CMH 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 Goods; 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 Goods Already Installed (leave blank if information is not available)

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

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

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

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

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

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

|  |
| --- |
|  |
|  |
|  |

**Part 10 – Questionnaire**

|  |  |
| --- | --- |
| **Information Required** | **To be Completed by Suppliers**(use separate sheet, if needed) |
| 1. What is the Serviceable Life of the product? (Please provide supporting documents)
 |  |
| 1. What are the details on parts and services covered in Warranty Service in addition to Part F?
 |  |
| 1. Any information / scope of safety test can be provided?
 |  |
| 1. Any green feature(s) from environment aspects of the offered product can be provided (with documentary proof if applicable)?

For example:1. The background illumination for the product should not contain more than 3 mg of mercury per lamp.
2. Any plastic parts should be manufactured without chlorinated paraffins flame retardants.
3. Component parts should not contain halogenated substances.
 |  |
| 1. Does the maintenance services (after warranty period) required executing by original manufacturer / sole maintenance body? If yes, is your company a sole maintenance body for the offered product?
 |  |
| 1. What is the payment schedule?
 |  |

**END**