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

**Request for Market Information (“RFI”) for
Supply, Delivery and Installation of Operating Lamp**

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

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

To : Project Director (CMHPO)

 (Attn. Team 1A)

[by fax: 2127 4795 or email: rhwleung@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 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)

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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.*

RFI (SE)

**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, delivery and installation of Operating Lamp (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 Operating Lamp.

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 has more than one Operating Lamp 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 Operating Lamp.**

**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*) |
| 1. Total weight of the proposed Goods
 | \_\_\_\_\_\_\_\_\_\_\_\_kg |
| 1. Floor loading requirement for the proposed Goods (if applicable)
 | \_\_\_\_\_\_\_\_\_\_\_ kPa |

**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 operating lamp 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** |
|  | **Goods to be Supplied** |
|  | The Goods is two sets of ceiling-mounted surgical LED light as stipulated in these Technical Specifications (hereinafter refers as “OT Lamp” or “Goods”). |  |  |
|  | **General Requirement** |
|  | Each set of surgical light shall be ceiling mounted and shall consist of at least one (1) unit of main lamphead and (1) unit of satellite light with the independent extension arm for horizontal movement, spring arm for vertical movement and double fork for light head movement. |  |  |
|  | The main light and satellite lamphead shall be mounted on the same central axle and compatible with the ceiling-mounted equipment to be installed therein. The reinforced central axis suspension shall provide continuous 360° rotary motions of all the swivel arms without stop. |  |  |
|  | The minimum false ceiling and mounting height of the surgical light, in order to achieve a standard headroom clearance, shall be at least 2000 mm. |  |  |
|  | The surgeons and operators shall be able to direct and position the surgical lights themselves by means of the sterilisable handles provided to all the light heads. |  |  |
|  | All the light head and the spring load arm system shall be sealed against dust. The light head shall be equipped with LED´s. |  |  |
|  | All the light heads shall be resistant to disinfecting agents. Unsterile positioning via surrounding handles that shall be integrated in the light head with smooth transition. The suspension arms of light heads shall be smooth surfaces, free from edges and screws. |  |  |
|  | The lamphead shall consist of detachable, autoclavable focusing handle at the centre of lamphead. Sterile positioning via the exchangeable, centrally located sterile handle. |  |  |
|  | Disposable focusing handle shall be provided. |  |  |
|  | The light heads shall produce overlapping identical light beams and extremely high in-depth illumination via collimators. |  |  |
|  | All the light heads shall produce highly cool, homogenous, symmetrically distributed, colour-true and cast shadow-free light by mixing cold and warm white LEDs.  |  |  |
|  | The colour temperature of the light heads shall be adjustable by using mixing cold and warm white LEDs in order to prevent coloured-cast shadow which is created by different colour type of LEDs. |  |  |
|  | All the light heads shall have a special mode for soft green ambient light patch for dedicated minimally invasive surgery. |  |  |
|  | The light heads shall be equipped with a dynamic electronic flux stability program to regulate LED current depending on LED temperature. The program shall ensure stable illumination when LEDs heat up and so the light intensity will not decrease in the entire operation.  |  |  |
|  | The light heads shall be HD video prepared for adapting a wireless full HD camera system. |  |  |
|  | **Functional and Performance Requirements of the Goods** |  |  |
|  | The central illuminance (Ec) measured at a distance of 1 metre from the light head shall be at least 120,000 lux. |  |  |
|  | The light intensity shall be adjustable in the range at least from 10,000 lux to 160,000 lux with 6 levels. It shall be adjustable from a control panel attached to the light head and a wall mounted control panel. |  |  |
|  | The light field diameter (d10), where the illuminance reaches 10% of the Ec, shall be adjustable in the range of 20 to 25cm. |  |  |
|  | The light field diameter (d50), where the illuminance reaches 50% of the Ec, shall be at least 11 cm.  |  |  |
|  | The depth of illumination (L1+L2), which is the working distance around 1 m below the light head and the illuminance reaches at least 20% of the Ec, shall be at least 110 cm.  |  |  |
|  | The depth of illumination (L1+L2), which is the working distance around 1 m below the light head and the illuminance reaches at least 60% of the Ec, shall be at least 52 cm. |  |  |
|  | The light shall produce adjustable colour temperature at 3,900K, 4,200K and 4,500K (up to user decision) and colour rendering index (CRI – Ra and R9) at least 95 and 90 respectively.  |  |  |
|  | The remaining illumination in 1m distance with the tube in relation to the Ec specified in the Section A3.1 shall be at least 100%. |  |  |
|  | The remaining illumination in 1m distance with the mask in relation to the Ec specified in the Section A3.1 shall be at least 55%. |  |  |
|  | The remaining illumination in 1m distance with a mask and a tube in relation to the Ec specified in the Section A3.1 shall be at least 55%. |  |  |
|  | The remaining illumination in 1m distance with two masks in relation to the Ec specified in the Section A3.1 shall be at least 45%. |  |  |
|  | The remaining illumination in 1m distance with two masks and a tube in relation to the Ec specified in the Section A3.1 shall be at least 45%. |  |  |
|  | The light head shall consist of at least 24 units of LED light source. |  |  |
|  | The total power consumption of the light head shall not exceed 70 VA. |  |  |
|  | The irradiance (Ee) measured at a distance of 1 metre from the light head in 100% illuminance (Ec) shall not exceed 500 w/m². |  |  |
|  | The service life of the LEDs shall be at least 55,000 hours. |  |  |
|  | The surgeons and operators shall be able to activate a boost mode by the one-touch command on a control panel attached to the light head and a wall mounted control panel. |  |  |
|  | The maximum light intensity shall be limited to 130,000 lux when the boost mode is not activated. The light intensity shall only be able to increase from 130,000 lux to the maximum of 160,000 lux when the boost mode is activated. |  |  |
|  | The surgeons and operators shall be able to activate a soft green ambient light by the one-touch command on a control panel attached to the light head and a wall control panel. |  |  |
|  | The illumination of soft green ambient light shall be adjustable in 5 levels with maximum light intensity at least 300 lux. |  |  |
|  | The diameter of the light head shall not exceed 700 mm, and the thickness of light head shall not exceed 145 mm. |  |  |
|  | The weight of the light head and double fork shall not exceed 16 kg. |  |  |
|  | The protection rating of the light head shall comply with IP 44. |  |  |
|  | An intuitive, user-friendly functions and easy-to-understand wall touchscreen control panel shall be provided to control light heads and wireless HD video camera. |  |  |
|  | The wall touchscreen control panel shall be capable to synchronize the parameter settings of the light heads and save presets |  |  |
|  | When the regulation PCB board in failure, the remaining illuminance shall be at least 80%. |  |  |
|  | When the peripheral LEDs in failure, the remaining illuminance shall be at least 95%. |  |  |
|  | When the central LEDs in failure, the remaining illuminance shall be at least 90%. |  |  |
|  | The central illuminance (Ec) measured at a distance of 1 metre from the light head shall be at least 120,000 lux. |  |  |
|  | Celing mounted |  |  |
|  | 1. The ceiling mounted surgical light shall be mounted to solid ceiling by means of an anchorage ring with diameter not greater than 420mm.
 |  |  |
|  | 1. The joint of extension arm and spring arm shall provide continuous 360° rotary motions without stop.
 |  |  |
|  | 1. The joint of spring arm and double fork shall provide continuous 360° rotary motions without stop
 |  |  |
|  | 1. The upper adjustment and downward adjustment of spring arm shall be at least +45° and -45° respectively.
 |  |  |
|  | 1. The joint of double fork shall provide at least 210° rotary motions without stop.
 |  |  |
|  | 1. The joint of double fork and light head shall provide at least 310° rotary motions without stop.
 |  |  |
|  | 1. The action radius of the two main OT light ceiling arm shall not be less than 1750mm and 1950mm respectively.
 |  |  |
|  | 1. Height adjustment of the main light and satellite light shall not be less than 1,130 mm.
 |  |  |
|  | **Safety and Product Standards**  |  |  |
| 9.1 | The OT Lamp shall comply with the following international standards (or equivalent national and other recognised standards or certifications): |  |  |
|  | 1. IEC 60601-1:2005
 |  |  |
|  | 1. IEC 60601-2-41:2021
 |  |  |
|  | 1. IEC 60601-1-2:2014
 |  |  |
| 1. IEC 60601-1-6:2010
 |  |  |
| 9.1 | If other fully equivalent recognized national standards are submitted, the tenderer shall provide a full text in English of the quoted standard and to state any deviation item above or below the specified equipment. |  |  |
|  | **Quality Management System (if applicable)** |  |  |
|  | 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 14971:2019 (or the latest version) certification or equivalent for the scope relevant to the Goods. |  |  |
|  | **Electricity Supply and Environmental Conditions (if applicable)** |  |  |
|  | The OT Lamp shall remain operational and within specification throughout the voltage range of 220V ± 6%, 50Hz ± 2%, single phase AC electrical supply. |  |  |
|  | **Other Requirements** |  |  |
|  | All components shall be free of burrs, sharp edges, protrusion and other defects which may cause hazard to operator. All surfaces and edges shall be smooth and non-abrasive. |  |  |
|  | The Goods shall be equipped with an over-current protective cutout device. |  |  |
|  | The Goods shall be effectively bonded to earth unless it is double insulated. |  |  |
|  | **Green Features** |  |  |
|  | Product components (circuit boards, electrical, electronic andplastic components) shall comply with RoHS. MaximumConcentration Values of the RoHS restricted substances are:i. Lead: 0.1% by weightii. Cadmium: 0.01% by weightiii. Mercury: 0.1% by weightiv. Hexavalent chromium: 0.1% by weightv. PBBs: 0.1% by weightvi. PBDEs: 0.1% by weight |  |  |
| **B** | **Implementation Services** |
|  | 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). |  |  |
|  | Installation and testing of equipment and accessories shall be performed by qualified personnel. |  |  |
|  | The equipment offered shall be completed with all essential accessories which are required for its normal operation. |  |  |
|  | No temporary storage space for any equipment shall be available within the construction site. |  |  |
|  | 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.  |  |  |
|  | Endorsement from Registered Structural Engineer registered under the Building Ordinance of the HKSAR that the offered equipment, after installation with all the components and accessories (if any), shall be safe for normal operation with the maximum loading capacity as stated in the equipment performance specifications published by the original equipment manufacturer(s) shall be provided. |  |  |
|  | The installation drawings and the as-fitted drawings showing the ceiling-mounted details of the equipment shall be certified by a Registered Structural Engineer registered under the Building Ordinance of the HKSAR to confirm, from structural point of view, that the installation is safe. |  |  |
|  | All structural calculations on equipment installation and any changes/revision shall be endorsed by a Registered Structural Engineer registered under the Building Ordinance of the HKSAR and submit to the Government. |  |  |
|  | All structural connections/ mounting of the equipment to the supporting frame/ concrete structure shall be witnessed and inspected by a competent person nominated and supervised by the Registered Structural Engineer, and the Registered Structural Engineer shall certify that the installation works are completed in accordance with the as-fitted drawings and the approved structural calculations. |  |  |
|  | Any structural works conducted by the successful tenderer shall be supervised by Authorized Person and/or Registered Structural Engineer as per requirement under Building Ordinance. |  |  |
|  | For equipment with loading larger than 100kg, Independent Checking Engineer (“ICE”) shall be appointed to examine the detailed design and method statements concerning the design, erection and use of the structural elements. |  |  |
|  | Compliance to Building Services and Builder’s Works Requirements |  |  |
|  | The equipment and installation shall be in compliance with the relevant requirements of the latest edition of “Code of Practice for Electricity (Wiring) Regulations”, issued by Electrical and Mechanical Services Department (“EMSD”). Electrical works by the successful Tenderer shall be carried out by Registered Electrical Workers (“REW”) of the appropriate grades, and the corresponding original completion certificates on the installation shall be signed by the REWs and send to Government for retention, in accordance with the current legislation. The result of testing (including insulation test) of the fixed electrical installation and installed equipment shall be stated on corresponding original completion certificate. All other works shall also be done by certified or registered workers / contractors and in the manners as required by the corresponding regulation as relevant. |  |  |
|  | All building services works including conduits, junction boxes, cables and pipe works, etc. shall be concealed and no surface mounting will be permitted unless otherwise so agreed.  |  |  |
|  | The successful tenderer shall be responsible for installation including electrical cabling / wiring works and other building services provisions in relation to the installation of the equipment. All materials and workmanship shall comply with latest editions of General Specification for Building Service Installations in Government Building of Hong Kong Special Administrative Region (and any corrigendum). |  |  |
|  | Relevant General Specification by Building Service Branch of ArchSD, Code of Practice for Electricity (Wiring) Regulations by the EMSD and Supply Rules of the Electrical Supply Authority as relevant, and shall be approved by the Government prior to the installation. |  |  |
|  | The successful tenderer shall be responsible for the builder’s works in relation to the installation of the equipment, including but not limited to opening and sealing of air-tight ceiling, etc. All installation works carried out by the Tenderer and / or its contractor shall meet the minimum standards set out in “General Specification for Building 2017 Edition”, or latest version, issued by ArchSD. |  |  |
|  | All installations shall comply with the latest edition of Code of Practice for Minimum Fire Services Installations and Equipment, and Inspection, Testing and Maintenance of installations and Equipment, prevailing FS circular letters and the standard set by the Loss Prevention Council. |  |  |
| **C** | **Training** |
|  | On-site maintenance and operational training shall be provided at no additional charges for a minimum of two maintenance and operation staff. |  |  |
| 1a. | 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, preventive maintenance procedures , calibration and alignment, adjustment, etc. |  |  |
|  | 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. |  |  |
| **D** | **Documentation** |
|  | Two sets each of English operation manuals and service manuals with principles of operation, operation instructions, preventive maintenance procedures, alignment and calibration procedures, full parts list and all circuit diagrams shall be provided with the Goods before or at the time with the delivery. |  |  |
| **E** | **Acceptance Tests** |
|  | The Goods shall be tested for acceptance at site by the supplier with the witness of representatives of CMH. 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. |  |  |
| **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 hours09:00 – 18:00 hours Monday to Friday, excluding public holidays09:00 - 13:00 Saturday, excluding Public Holiday |  |  |
|  | 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. |  |  |
| **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 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. |  |  |
| **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 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 OT Lamp can meet with the standards stated in Column I* ***by inserting a tick in an appropriate box under Column III****. If your proposed OT Lamp does not meet the standards stated in Column I, please indicate the equivalent standards met by your proposed OT Lamp 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 |
| IEC 60601-1:2005 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance |  |  |  |
| IEC 60601-2-41:2021 | Medical electrical equipment - Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis |  |  |  |
| IEC 60601-1-2:2014 | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests |  |  |  |
| IEC 60601-1-6:2010 | Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability |  |  |  |
| ISO 13485:2016 | Medical devices — Quality management systems |  |  |  |
| ISO 14971:2019 | Medical devices — Application of risk management to medical devices |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
| 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 |
|  | Dose the proposed System have marketing authorization of Food and Drug Administration (FDA) of the United States? |  |  |
|  | If the proposed System has marketing authorization of FDA, please specify below the type of marketing authorization (i.e. approval, clearance or exemption). \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |
|  | Does the proposed System have marketing authorization of the European Union (EU) for affixing of CE marking on the product? |  |  |
|  | 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.
 |  |  |
|  | 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 : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |
|  | Has your proposed System been listed in the MDACS of the Department of Health?  |  |  |
|  | 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 and installation of the Goods as more particularly specified in **section A1.1 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 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) |  |

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

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

|  |  |  |
| --- | --- | --- |
| **Aspect** | **Description of Selected Desirable Features** | **Any Additional Charge to Total One-time Chargeas Specified in Part 7(a)**(Please tick whichever is applicable) |
|  |
|  |  |  |
|  |  |  |
|  |  |  |

**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’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 publd holidays and 9 am to 1pm on Saturday 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’s 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 System (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**