The DIRCETROATE OF ROYAL MEDICAL SERVICES THE INSTITUE OF BIOMEDICAL TECHNOLOGY



| 4 | Steam Sterilizer | Qty. (1) |
|--------|------------------|----------|
| Item 1 | | |

IMPORTANT NOTE:

Vendors are required to fill out the product details, compliance information, and brochure reference page number in the columns below

TECHNICAL SPECIFICATIONS:

The unit must meet or exceed the requirements listed in the table below.

| P | roduct Details |
|---|----------------|
| Name of Manufacturer | |
| Model/ catalogue number | |
| Country of Origin for the offered model | |
| Country where the manufacturer is based | |
| Delivery time | |
| Full warranty period | |
| FDA clearance OR CE Mark | |

| | Minimum Requirements | Compliance (Y/U), Notes | Brochure Page No. |
|---|--|-------------------------|-------------------|
| 1 | General: | | |
| | a- Steam sterilizer for the sterilization of instruments, textiles and rubber goods. | | |
| | b- Constructed in accordance to European standard (EN 285) and/or to American standard (FDA). | | |
| | c- Double-door model. | | |
| | d- Side Panels | | |
| | e- Easy access for technical maintenance staff. | | |
| | f- Should work on central steam supply | | |
| | g- Carrier components should be constructed from high quality stainless steel or copper. | | |
| | h- Frame and outer easing of the sterilizer should be made from robust anticorrosive material. | e | |



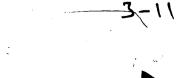


| | Minimum Requirements | Compliance (Y/N) , Notes | Brochure Page No. |
|---|--|--------------------------|----------------------|
| 2 | Sterilization Pressure Vessel: | | |
| | a- Made from high quality stainless steel 316L or 316Ti. | | |
| | b- Vessel designed and manufactured according to pressure equipment directive (PED) No. 97/23/EC and/or ASME. | | |
| | c- Capacity: 8 STU baskets | | |
| | d- Well insulated Steam Jacket made from high quality stainless steel 316 L or higher. | | |
| | e- Rails for loading carts made from Stainless steel 316L or higher. | | |
| 3 | Chamber Doors: | | |
| | a- Vertical sliding double doors | | |
| | b- Durable long service life door gasket, gasket should be replaced freely during warranty period or as recommended in P.P.M plan. | | |
| 4 | Vacuum Device: | | |
| | a- Powerful water ring vacuum pump that provide fast removal of air during protreatment and fast effective drying, vacuum pump should be connected to soft water only. | | |
| | b- Low noise pump. | | |
| | c- Durable efficient long service life heat exchangers that provide steam cooling during drain phase, heat exchangers should be connected to cold soft water only. | | |
| 5 | Control System and operating panel: | | |
| | a- Pressure transducer for the precise control of pressure and vacuum in the chamber. | | |





| | Minimum Requirements | Compliance (Y/N); Notes | Brochure Page No. |
|---|--|-------------------------|----------------------|
| | b- Dual Resistance temperature sensors PT 100 for the precise control and record of temperature in the chamber. | - 1 | |
| | c- Pressure transducer and/or temperature sensor for the precise control of pressure and temperature in the jacket. | | |
| | d- Operating panel with a large LCD screen indicating selected program, phase, door position, time and error notifications in English language. | | |
| | e- Auto diagnostic system providing error codes on display in case of failure accompanied with audio notification. | ! | |
| | f- Integrated printer for sterilization process including time, program, error codes, temperature and pressure and result of sterilization process. | | |
| 6 | Safety features: | | |
| | a- Chamber and jacket should be equipped with overpressure safety valves, or one safety valve to be installed on main steam supply. | | |
| | b- Doors should be equipped with safety lock (latch) to prevent door opening during operation. | | |
| 7 | Sterilization and testing programs at least: | | |
| | a- Wrapped instruments/textiles 134° C. | | |
| | b- Rubber goods 121° C. | | |
| | c- Rapid Cycle 134° C. | | |
| | d- Vacuum leak test cycle | | |
| | e- Bowie & Dick test cycle | | |
| 8 | Accessories: | | |



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| | Minimum Requirements | Compliance (Y/N), Notes | Brochure Page No. |
|----|---|-------------------------|----------------------|
| | a- One batch rack: 2 shelves made from high quality stainless steel capacity of 8 STU baskets | | |
| | b- Two transfer trolleys: made from high quality robust anticorrosive material, with push handle and four antistatic castors | | |
| | c- 48 stainless steel STU baskets made from stainless steel. | | |
| 9 | Air Compressor (should be quoted separately if needed) with the following specifications: | | |
| | 1. From a well-known manufacturer | | 1. |
| | 2. Oil free or oil injected type | | |
| | 3. Complete with air dryer. | | |
| | 4. Flow rate to be sufficient to operate both autoclaves | 1 | |
| | 5. Auto drain of condensate mechanism | | |
| | 6. Tank capacity ≥ 100 L | | |
| 10 | Pre-installation and installation shall include: | | |
| | a- Must be done according to manufacture requirements as mentioned in the installatio manual and according to international standards | n | |
| | b- Installation must guarantee adequate remaining spaces for service reasons | ng | |
| | c- Steam supply line should be connected pressure regulator (Spirax or TLV), pressugauge, steam filter, steam trap | re | |
| | a- Water supply lines should be connected manual gauge and strainer. | to | |
| | b- Air supply line should be connected to regulator, manual gauge and water trap. | air | |





| | Minimum Requirements | Gompliance (Y/N), Notes | Brochure |
|----|---|-------------------------|----------|
| | c- Any required additional civil electromechanical work is the sole responsibility of the supplier including door modification to insert and install the equipment in C.S.S.D department in Prince Zaid Bin Al-Hussein Military Hospital (Al-Tafeeleh), bidders should visit the site before submitting quotations | | Page No. |
| | d- Any modification of the existing stainless steel cladding is the responsibility of the supplier | | |
| 11 | PPM (Planned preventive maintenance): shall be the sole responsibility of the supplier, it shall include all labor works and any needed service parts recommended to be changed after certain hours or cycles. | | : |
| 12 | Qualifications and after sales service: The technical bid should contain all the necessary documents (training certificates) to prove the capability of the bidders for supplying and installing a trouble free equipment meeting the quality standards and technical specifications of the manufacturer and the ability of the bidders for providing efficient after sales service conducted by at least two certified biomedical engineers. | | |
| 13 | Training (quoted separately) Offers must include a certified service training program at a reputable center abroad recognized by the manufacturer for at least one biomedical engineer or technician as in special terms | | |



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SPECIAL TERMS

- Offers not complying with any of the <u>special terms or the technical specifications</u> shall be considered non-conforming with tender requirements.
- Any vendor providing FORGED documents shall be disqualified from the current tender and banned from participating in any future RMS tenders.
 - 1. All equipment must be the most recently released model/version which is equal to or higher than the range of the specifications of the required system (low, mid or high) and equal to or higher than the level of technology and required options mentioned in the technical specifications.

2. Required certificates:

- 2.1 For equipment of US origin, a copy of a certificate of FDA approval & the relevant 510K clearance for selling to US healthcare facilities for the offered model <u>must be submitted</u> with the technical offer.
- 2.2 For equipment of other origins, a copy of either a CE certificate with the relevant CE number (MDD)/TÜV/BSI/UL OR a certificate of FDA approval & the relevant 510K clearance for selling to US healthcare facilities for the offered model must be submitted with the technical offer.
- 2.3 Only for class I medical equipment, submission of a copy of Declaration of Conformity certificate (MDD) for the offered model shall be accepted.
- 2.4 With each offer, bidders must provide a formally endorsed document issued by the manufacturer stating that the bidder is the sole certified agent / distributor for the offered item.
- 2.5 In all of the above cases (except 2.4) certificates must be formally endorsed by JFDA.

3. Country of origin:

i. The country of origin of the main part (s) of the system must be one of the following:

USA, Canada, Japan, UK, Sweden, Finland, Denmark, Switzerland, Belgium, Germany, France, Netherlands, Spain, Norway, Italy, Ireland, Austria, New Zealand, Australia & Czech Republic.

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- ii. Accessories and consumables (as determined by the purchasing committee) may be manufactured in other countries and/or by different manufacturers.
- iii. All offered items must be approved for sale in the same country of origin.
- iv. Vendors must specify the origin of all offered items and accessories in the technical offer.
- v. Equipment manufactured by reputable companies based in any of the countries mentioned in (3.i) will be taken into consideration regardless of the manufacturing site only:
 - a. If they are approved for sale in the same county of origin (an original and officially endorsed free-sale certificate from an authorised body must be included in the offer.

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- b. If they are approved for sale in at least three of the countries mentioned in (3.1) (an original and officially endorsed free-sale certificate from an authorised body in those countries must be included in the offer).
- vi. Bidders must submit their reservations/queries regarding tender specifications and/or special terms within the first third of the tender closing period starting from the tender announcement date. Reservations/queries submitted after the end of this period shall be rejected.

4. Warranty:

- i. Offers must include a full warranty including spare parts and labour for a period of a minimum of 24 months from the date of installation.
- ii. If at any time during the warranty period the item becomes inoperative due to a technical fault the item must then be repaired by the supplier local agent within a period of fourteen days from written notification, otherwise the supplier must replace the item with a new identical functioning one and will endure a penalty determined by the Royal Medical Services for each day of the downtime of the system. In case the item was replaced by a new one, the warranty period mentioned in (4.i) above will start from the installation and commissioning date of the new item.
- 5. One set of operation manual(s) and one set of service manual(s) including schematics and a spare-part list must be delivered with each unit, CD/DVD is acceptable. For large tenders, a certain agreed percentage of manuals per item may be agreed upon.



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- 6. Where applicable, pre-installation shall be the sole responsibility of the supplier. Pre-installation shall include removal of old system(s), any civil work, electrical work or site modification(s) necessary to accommodate the new system(s) according to manufacturers' specifications and safety standards in addition to the work required for bringing back the site to the same working conditions as before installing the new system(s).
- 7. Power requirements: where applicable either single phase 220V, 50Hz or 3-phase 380V. Systems with external transformers are considered conforming only if clearly stated in the technical specifications.
- 8. Technical offers must include clear original technical brochures/catalogues for all offered items.
- 9. Offers must include fully detailed technical offers and compliance sheets as a soft copy (either Microsoft office or Microsoft excel format) in addition to a hard copy, mentioning the exact model/catalogue number and country of origin of the offered item(s), full technical description/specifications and any accessories or options included in the offer.
- 10. Compliance sheets must be as per the tabular format of the technical specifications in the tender documents, listing the required specifications on one column and a Yes or NO response to each point in the adjacent column, with reference to page and line numbers in the relevant technical brochure. Offers not complying with this term shall be rejected.

11. Accessories and consumables:

- i. Any accessories and consumable items necessary to operate the offered system must be clearly identified and priced separately.
- ii. Technical offers must include a priced list for accessories and consumables as a hard copy in addition to a soft copy (either Microsoft office or Microsoft excel format) with prices fixed for a period of five years from the date of installation and commissioning with a maximum annual increase of 2%, any essential item not listed will be considered free of charge.
- iii. Accessories and consumables must be priced according to their delivery destination either to Queen Alia International Airport or to RMS Main Medical Stores.
- iv. Where applicable, a start-up kit of accessories and consumable items must be provided with each system on a free-of-charge basis.

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12. Spare Parts:

- i. Technical offers must include a comprehensive and priced spare parts list as a hard copy in addition to a soft copy (either Microsoft office or Microsoft excel format) valid for a minimum period of five years with a maximum annual increase of 2%, commencing at the end date of the warranty period, any essential item not listed will be considered free of charge.
- ii. Spare parts must be priced according to their delivery destination either to Queen Alia International Airport or to RMS Main Medical Stores.
- 13. Spare parts, consumables and accessories availability must be guaranteed for a minimum period of ten years starting from the date of installation and commissioning.

14. Tender Awards:

- i. For the final list of offers having a chance of winning the award, the awarding process shall be based on the accumulative value of both the offered item and its' running cost (<u>Total Cost of Ownership</u>) over a period of seven years from the date of installation and commissioning. Only offers with the lowest total cost of ownership over a period of seven years from the date of installation and commissioning shall qualify for the award.
- ii. Running cost includes the value of consumables, accessories needed to operate the system over the same period as well as the cost of any service contract (where applicable).

15. For PC/Laptop based systems:

- i. Complete restoration medium (CD/DVD/etc.) of the operating system and the application software must be supplied.
- ii. Where locally supplied computers or laptops are offered, only computers/laptops from Apple, hp/Compaq, Lenovo, Dell, fujtisu or Toshiba will be accepted, offered models must be the latest available version upon delivery.
- iii. Where locally supplied printers are offered only the following types and brands are accepted: HP, SAMSUNG, OKI, CANON, EPSON.
- 16. Pricing must include services of sale, shipment, transportation, delivery from port to site or to Main Medical Stores, installation, pre-installation (if needed), training, commissioning, warranty and bringing the equipment into service.



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- 17. Custom clearance of goods shall be the responsibility of the Jordanian Armed Forces (JAF), however, suppliers shall bear all costs incurred by handling charges and any demurrage charges or extra expenses incurred by the port's corporation (including expenses caused by delay in presenting the necessary shipment documents for either clearing or transporting the goods to the required location mentioned in the final order, delivery note issuing charges, unloading charges, local shipping charges etc.). The supplier is also responsible for providing of all relevant shipping documents, together with the delivery order(s).
- 18. DRMS has the right to increase or decrease the awarded quantities by a percentage not exceeding 30% after the final order notification with the same prices, terms and conditions of the original contract upon DRMS request and approval of the awarded party.
- 19. The supplier must furnish DRMS with a guarantee stamped and legalized by the Notary Public equals to (115%) of the total value of the awarded equipment valid for twelvemonths from the date of final acceptance of the equipment by DRMS.

20. Training:

- i. For items where service training courses for the offered system are usually conducted abroad, offers must include a certified service training program at a reputable center abroad recognized by the manufacturer for at least one biomedical engineer or biomedical technician; all costs inclusive, air tickets, , boarding, commuting, accommodation (minimum 3 star hotel on full board basis) and any extra costs.
- ii. For items where user training courses for the offered item are usually conducted abroad, offers must include a certified operator training program at a reputable center abroad recognized by the manufacturer for at least one operator; all costs inclusive, air tickets,, boarding, commuting, accommodation (minimum 3 star hotel on full board basis) and any extra costs.
- The period of the training courses must be according to the manufacturer's program excluding travelling days, and must be stated clearly in the technical offer.
- iv. Training Programs must conform to the following standards:
 - i. User training must comprise understanding and use of operation manual(s), correct and safe operation of the equipment, as well as user preventive maintenance and calibration.









- ii. Service training must comprise: theory, understanding and use of service manual(s), calibration, preventive maintenance procedure, and practical troubleshooting and repair exercises, and must be conducted by professional instructors employed or authorized by the system manufacturer.
- iii. Service training must be conducted on a system of identical make, model, and configuration to that purchased by DRMS, and designated by the manufacturer or the local agent for training purposes.
- iv. Certificates must be endorsed and officially sealed by the system manufacturer, legally empowering trainees to engage in user and service activities according to operation and service manual(s).
- v. Where applicable, offers must include on-site user and service training.