Annex A

Technical Specifications for Water Purification System
Technical Specifications for Water Purification System

1. Functional Requirements

1.1 This system unit is intended for complete lab autonomy and best adaptation to laboratory water needs, the water purification system will deliver pure & ultrapure water directly from tap water.

2. General Requirements

2.1 To guarantee compliance with minimum laboratory safety requirements, and to ensure that the water purification system meets internationally-recognized safety norms, the water purification system shall be listed with Underwriters Laboratories (both UL and ULC), and will carry the CE mark, indicating compliance with European Union EC Directives

2.2 The system shall be comprised of water purification unit containing reverse osmosis, electro-deionisation, ion-exchange and activated carbon technologies and polishing device.

2.3 To reduce the consumable replacement, the water system will include an EDI (ElectroDeIonisation) module that does not require softening pre-treatment.

2.4 The ultrapure water system delivery unit will dispense ultrapure water in two modes easily accessible: variable flow and volumetric dispensing

2.5 The ultrapure water system delivery unit is designed so that regular lab containers, such as cylinders and flasks, can be filled without the need to hold them. The system will also incorporate a volumetric dispensing function capable of automatically dispensing of ultra pure water from 0.1 L up to 60 L.

2.6 To avoid maintenance errors and to improve traceability, the internal primary consumable water purification cartridges will have a built-in RFID tag

2.7 The ultrapure water system delivery unit will be adapted to easy ultrapure water dispense in all containers regularly used in the laboratory

2.8 The ultrapure water system delivery unit will incorporate a fully comprehensive, graphic color LCD display to provide information 1) on system status and performance parameters, 2) on routine maintenance needs, and 3) on alarms for troubleshooting in the event of system malfunction. Graphic icons and operating control values must also be available as standard.

2.9 The ultrapure water system built-in resistivity and TOC monitors will be calibrated according to international norms and standards.

2.10 To comply with USP requirements, the resistivity meter shall be able to display the non-temperature-compensated resistivity.
2.11 The internal primary consumable water purification cartridge must attach to the water system without threaded fittings, screws, clamps, or locking tabs.

2.12 To ensure on-time reordering of the pre-treatment consumables, the system will have automatic warnings.

2.13 The ultrapure water system will have a 2 years life time built-in UV lamp with emission at 185 and 254 nm wavelength.

2.14 The water system will have a built-in delivery pump for optimum ultrapure water delivery.

2.15 To prevent deterioration of water quality during periods of non-use, the ultrapure water system will be able to recirculate water to maintain high water quality.

2.16 The system will have a choice of point-of-use final filter options, including a 0.22 micron final filter, a point-of-use ultrafilter, and an FDA-registered medical device, to meet individual needs.

2.17 The water system will incorporate a built-in Quick Reference Guide for immediate understanding of the main operations.

2.18 There will be constant communication between the ultrapure water system and the feed tank to ensure that there is always a constant supply of water to the polishing portion of the system.

2.19 The water purification system will have a special mode for short periods of non usage (up to one month).

2.20 To prevent bacteria development in the storage tank, the system will combine a 254 nm UV lamp sanitizing water at the inlet of the tank and a 254 nm UV lamp inside the tank for prevention of biofilm development.

3. Electrical Requirements

3.1 The system shall be capable of operating directly from a 230V ± 10%, 50 ± 2 Hertz, single phase AC supply.

3.2 The system shall fully conform to IEC 60601-1 general requirement for safety of electrical equipment.

3.3 The unit shall have built-in A/C line conditioner to provide isolation from voltage fluctuations and electrical noise interference.

3.5 The unit shall be equipped with self-tripping circuit breaker for protection against overload.
4. **Safety Requirements**

4.1 The body of the unit shall be constructed with sufficient degree of resistance against safety hazards caused by liquid spillage, humidity, sterilisation and disinfection.

4.2 The enclosure shall be secure and provide adequate protection against moving and electrically energised parts.

4.3 Switches and controls should be protected against penetration of fluids.

4.4 Switches and controls shall be protected against accidental setting changes.

4.5 The controls (i.e. switches, knobs, etc.) should be visible and clearly identified, and their function should be self-evident. Device design should prevent misinterpretation of displays and controls settings.

4.6 The unit shall resist tipping over during use and transport.

5. **Technical Requirements**

5.1 The Tenderer shall furnish full technical specifications of the tendered Article together with the tender submission.

6. **Standards**

6.1 The system shall fully conform to the following:
- a. IEC 60601-1, General safety requirements for medical electrical equipment;
- b. IEC 60601-1-2, General safety requirements for Electromagnetic Compatibility – Requirements and tests;
- c. Particular requirements for safety and performance for water purification system.
- e. Shall have FDA clearance.

6.2 The system shall fully comply with the latest Republic of Singapore Radiation Protection Act and Regulation for Ultrasound instrument. The nature and extent of such protection shall be to the satisfaction of the Health Science Authority (HSA) and all costs (if any) incurred to comply with the regulation shall be borne by the Tenderer.

6.3 The Contractors will comply with Health Science Authority (HSA) Medical Device Regulation requirements for all classes of medical devices. A copy of the HSA registration certificate must be submitted together with the tender submission.

7. **Standard Accessories**

7.1 All standard accessories shall be listed with itemised prices and be included in the system base price.
8. Optional Accessories

8.1 All optional accessories not included in the standard accessories shall be listed with itemised prices.

9. Installation / Commissioning Requirements

9.1 The Contractor shall inspect the site and fully acquaint himself with the nature of the work and the local conditions and facilities available, including water, drainage, ventilation and air-conditioning, where the Article is to be installed, before submitting his tender. He should also utilise other means he may prefer or consider necessary in order to fully ascertain other matters, site accessibility to equipment, conditions or constructions that may have a bearing on, or in any way affect the preparation of his tender. No claim for extra payment will be entertained by the Hospital owing to the Contractor’s neglect in this regard and any unforeseen difficulties for which provision is not made. This will in no way relieve the Contractor from the full execution of all works necessary to complete the installation. A Contractor, by the fact of submission of a tender, shall be deemed to have accepted all conditions and stipulations of this clause, which shall be binding on the Contractor.

9.2 For the testing & commissioning and thereafter for the warranty preventive maintenance & corrective maintenance or on service contract preventive maintenance & corrective maintenance, the contractor shall be represented by competent staff, suitably equipped with all necessary calibrated test and measuring instruments including electrical safety analyser with printout, who shall test and commission or performing the preventive maintenance the Articles in the presence of and to the satisfaction of the Company’s authorised representatives. The Contractor must perform the electrical leakage safety test for the equipment during commissioning and for every preventive maintenance servicing during warranty preventive maintenance & corrective maintenance or on service contract preventive maintenance & corrective maintenance with no cost to the hospital. ( Please refer SCC.3, Clause 11 for details )

9.3 All mains operated electrical Articles shall be complete with suitably insulated and sheathed three-core hospital grade flexible power cords of voltage and current rating appropriate to the Articles. Article for operating theatre shall be supplied with flexible power cords each of not less than 5m length, although the exact length shall be negotiable later. The flexible power cord shall be fitted with three-pin, high impact, unbreakable nylon body electrical plug meeting BS 1363/A or equivalent. The plug shall be of good quality consistent with hospital safety, moulded construction type and shall be equivalent to “Volex V.1307W”, BICC 3583-07”, or MK Toughplug”, 13A nylon unbreakable plugs. The plug shall be wired in conformance with sub-clause 6.5 of IEC 60601-1.

10. Additional Requirements

10.1 The supplied equipment and accessories must be of hospital-grade and shall comply with national and internationally recognised Standards and applicable Standard Systems.
10.2 The Contractor shall provide test certificates from an internationally recognised testing body attesting to compliance with recognised standards. If certificates for the STATED compliance are not provided during the submission, it shall be considered as non-compliant to the standard.

10.3 The Contractor is expected to equip with all necessary test tools and successfully commission the Article 14 days from the date of delivery. Failure of which the Company has the right to return the Article to the Contractor. No claim for payment will be entertained by the Company. A contractor, by the fact of submission of the tender shall be deemed to have accepted all conditions and stipulations of this clause, which shall be binding on the Contractor.

10.4 The testing and commissioning of the Article shall be in accordance with clause 11 of *SCC.3 called under Material Management Department. No payment shall be made if any of the stated requirements under this clause were not met. Notwithstanding the incomplete acceptance of the Article, the Company has the right to utilise the Article while waiting for any incomplete supply to be delivered.

10.5 The Contractor should be a direct representative/distributor of the manufacturer for all Articles including accessories.

10.6 The Contractors shall submit a letter of appointment from the manufacturer as sole agent in Singapore for the articles offered. The Contractor shall also specify:
   a) The number of years that they have been appointed agent; and
   b) The expiry date of the current agency agreement;
   c) The expected date of discontinuation of this product.

10.7 The warranty shall cover unlimited breakdown service calls, calibration and software upgrades, at no additional cost. The preventive maintenance of the unit shall be in accordance with the manufacturer's procedure and interval. The regular preventive maintenance shall include testing in compliance to IEC 60601.1. The Contractor shall at the time of submission, provide a copy of the preventive maintenance checklist, method and procedures. The Contractor shall provide back-up units during the warranty period while the unit is undergoing corrective repair by the Contractor.

10.8 In the event of equipment breakdown and the downtime exceeds 24 hours, the Contractor shall be responsible for arranging a loan unit of similar capacity to be used by the Company. All cost shall be borne by the Contractor.

10.9 The successful Contractor shall provide appropriate In-service training for Physicians, Nurses, Clinical staff, Laboratory Technologist, etc and Technical Service Training for Biomedical Engineers/Technicians. A qualified full time trainer shall conduct the training. In-service training shall be provided by qualified clinical instructors who are not sales personnel. Technical service training shall be provided by a qualified engineer. The technical service training shall be comprehensive and provided to a level such that the Company’s nominated service personnel are able to: a. Apply or handle; and b. Install, repair, calibrate, maintain
or overhaul all models of equipment purchased from the Contractor. The outline of the Technical service training programme must include - installation instructions; system overview with block diagram; detailed theory of operation; detailed preventive maintenance procedures; detailed calibration and performance checks; detailed trouble shooting; overhaul procedures. Full warranties for all equipment shall remain in place until at least training for the in-house engineer s has been completed. Following the completion of training, the Contractor shall, if requested, certify that trained personnel have completed the Contractor’s training program. All In-service and technical service training shall be dedicated to the Company and conducted at the Company’s facilities unless otherwise agreed upon. The Contractor at the point of training shall provide the Article. All cost shall be borne by the Contractor.

10.10 The Contractor shall submit full details of system, inclusive of a complete list of options currently available and options that will be available or are currently under development.

10.11 The Company will be entitled to purchase all replacement parts, components, subassemblies and peripheral devices as needed for the maintenance and repair of each model of equipment purchased from the successful Contractor at the fair market price. No excessive handling or shipping charges will be applied to these purchases. The successful Contractor must expedite all shipments and not withhold shipments in order to increase equipment downtime to the Company or for any other reasons.

10.12 The Company has the right to use any service representative of his choosing, including in- house, third party or independent contractor. These representatives have the right to repair, install, calibrate, maintain or overhaul all models of equipment purchased from the successful Tender. The Company’s representatives shall be afforded the privilege of ordering all necessary repair parts and components from the successful Contractor for each model of equipment purchased at a fair market price.

10.13 The Tender shall guarantee the availability and sale directly to Company or its representative of spare parts, schematics, parts lists, troubleshooting manuals, operator's instruction manuals, and all other technical data for the life of the equipment and that replacement of defective parts or other equipment maintenance by Company or its representative will not affect warranty conditions.

10.14 The Company has the right to use and operate all hardware and software for the purposes of operating, repairing, or calibrating the equipment. The Company has the right to allow her designated service representative to use all software for the repair and calibration of the equipment purchased.

10.15 The supply of the system computer must be from a registered computer manufacturer and be supported by the manufacturer’s service center. The model must fulfill the basic safety requirements of Radio Frequency Interference, Electromagnetic Immunity and Safety for Information Technology Equipment. Proof of safety compliance must be presented during the submission.
10.16 The Company has the right to send her designated service representatives to the manufacturer’s service training school to receive sufficient, any or all, technical training to allow the representative to repair and calibrate the equipment purchased.

10.17 All documentation, software and manuals become the sole property of the Company.

10.18 Upon sale or transfer of the equipment purchased within and/or outside of Singapore, the Company’s shall have the right to transfer any or all hardware, software, documentation and manuals to the new purchaser of the equipment.

10.19 The Contractor is advice to check for incompleteness and misleading information that may result in disqualification.

10.20 All Contractors are to comply with all requirements stated in the Company Standard Conditions of Contract - *SCC.3.

10.21 Failure to comply with any of the above requirements may result in the rejection of the offer.

* SCC.3 is available from Material Management Department. All Tenderers are to acquaint themselves with the details requirements set out in SCC.3.
A. PERFORMANCE SUMMARY of Water Purification System

Tenderer/Company : ____________________________________________

Description Of system/Unit : ______________________________________

Manufacturer/model : ____________________________________________

Year of model : _________________________________________________

Country of origin : ______________________________________________

Warranty period : ________________________________________________

(*Please delete where applicable)

You are advised to be truthful in your submission. Nothing is to be left blank. Where compulsory submissions are required, kindly furnish as required to avoid disqualification. Each option offered must be accompanied by a Performance Summary.

1. FULL COMPLIANT with technical specifications * Yes/No

2. NON-COMPLIANT with technical specifications (details shall be specified clearly on a separate sheet in text format) pls state nos. only

3. Listed with Underwriters Laboratories (both UL and ULC), and will carry the CE mark, indicating compliance with European Union EC Directives. * Yes/No

4. unit containing reverse osmosis, electro-deionisation, ion-exchange and activated carbon technologies and polishing device. * Yes/No

5. Include an EDI (ElectroDeIonisation) module that does not require softening pre-treatment. * Yes/No

6. Unit will dispense ultrapure water in two modes: variable flow and volumetric dispensing * Yes/No

7. Volumetric dispensing function capable of automatically dispensing water from 0.1 L up to 60 L * Yes/No

8. Water purification cartridges have a built-in RFID tag * Yes/No

9. A color LCD display to provide information on system status, performance parameters, system error, graphic icons and operating control values must also be available as standard. * Yes/No
10. Built-in resistivity and TOC monitors will be calibrated according to international norms and standards. * Yes/No

11. The resistivity meter shall be able to display the non-temperature-compensated resistivity. * Yes/No

12. Water purification cartridge must attach to the water system without trenched fittings, screws, clamps, or locking tabs. * Yes/No

13. Automatic warnings for change of pre-treatment consumables * Yes/No

14. Built-in UV lamp with emission at 185 and 254 nm wavelength. * Yes/No

15. A built-in delivery pump for optimum ultrapure water delivery. * Yes/No

16. Be able to recirculate water to maintain high water quality. * Yes/No

17. Have a choice of point-of-use final filter options * Yes/No

18. Built-in Quick Reference Guide for the operations * Yes/No

19. A special mode for short periods of non-usage (up to one month) * Yes/No

20. A 254 nm UV lamp sanitizing water at the inlet of the tank * Yes/No

21. A 254 nm UV lamp inside the tank * Yes/No

22. **POWER CORD**
   a. Safety catch for securing the line power cord (casing interface) to the unit casing * Yes/No
   b. Type of power plug use, e.g. single phase moulded 13A plug, 20A, etc. pls specify ________________

23. **FUZEHOLDER (if applicable)**
   a. Accessible from outer chassis * Yes/No
   b. Others pls specify ________________

24. **LIQUID-SPILL PROOF** * Yes/No
   a. Degree of protection - IP code pls specify ________________

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25. **SYSTEM NOISE LEVEL, dBA**
   pls specify ________________
   when in full operation

26. **INTERFACE**
   a. capability of connecting and interfacing
to other computers  
   * Yes/No

   b. type of interface port  
   pls specify ________________
   (USB, RS 232, etc)

27. **BATTERY OPERATED** (if applicable)

   a. Battery type  
   pls specify ________________

   b. Battery rating  
   pls specify ________________

   c. Full charging time  
   pls specify ________________

   d. Battery operating time, hr  
   pls specify ________________

   e. Built-in charger  
   * Yes/No

28. **ELECTRICAL SAFETY**

   a. Safety Class  
   pls specify  
   * I / II / III

   b. Type of protection  
   pls specify  
   * B / BF / CF

29. **STANDARDS OF COMPLIANCE**  
   pls specify ________________
   (certificates of conformity to be provided)

   a. Can your proposed system comply to International
   standards such as International Electrotechnical
   Commission (IEC), British Standards (BS),
   European Standard (EN), etc?  
   * Yes/No

   b. Kindly specify the type of compliance and its class.  
   ________________

   c. A certificate for each compliance is required (previous
   compliance for the same model may be accepted
   as a reference)
   ________________

   i) IEC/EN 60601-1, general requirements for electrical for
   measurements, control and laboratory use or equivalent  
   * Yes/No

   ii) IEC/EN 60601-1-2, Electromagnetic Compatibility  
   * Yes/No

   iii) IEC/EN 61000-4-x series safety requirements and tests
   for Electromagnetic Compatibility, Immunity  
   * Yes/No
iv) IEC/EN 60529 (1989), Degrees of protection provided by enclosures (IP code).  
- IP code pls specify __________________________

v) International available standards in the particular requirements* Yes/No for safety and performance for the tendered Article
- if yes, pls specify the reference standard __________________________

vi) FDA approval

vii) Others (pls specify) __________________________

* If certificates for the compliance are not provided during the submission, it shall be considered as non-compliant to the standard.

30. **POWER CONSUMPTION**

a. Standby Operation, KVA/KW/Amp pls specify __________________________

b. Normal Operation, KVA/KW/Amp pls specify __________________________

c. Heat Dissipation

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### 31. WARRANTY & POST-WARRANTY SERVICE CONTRACT (p/s submit with each offer)

<table>
<thead>
<tr>
<th>Description</th>
<th>Warranty Period</th>
<th>1st year after warranty</th>
<th>2nd year after warranty</th>
<th>3rd year after warranty</th>
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<tr>
<td>Frequency of Preventive maintenance (nos. of times per year) recommended by manufacturer: _______ (Note: Vendor must submit confirmation documents from manufacturer.)</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
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<td>Frequency of Preventive maintenance (nos. of times per year) Hospital Requirement: Frequency of PM during warranty: 2 times or more per year</td>
<td>Frequency of PM: _____ During Warranty Period /per year</td>
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<td>Annual Charges for Preventive Maintenance(PM) only. (The cost which covers all labour and transportation cost of providing PM only periodically within a year and corrective maintenance is not included)</td>
<td>Not Applicable</td>
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<td>Annual Charges for Preventive Maintenance(PM) And unlimited Breakdown Repair calls (The cost which covers all labours transportation, on-site response for providing both PM and corrective maintenance except replacement parts )</td>
<td>Not Applicable</td>
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<td>Annual Charges for Preventive Maintenance(PM) And unlimited Breakdown Repair calls and all Replacements parts Including software upgrades, etc. (The cost for comprehensive maintenance which covers all labours, transportation, on-site response for providing both PM and corrective maintenance and parts including software upgrades, etc.)</td>
<td>Not Applicable</td>
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32. SERVICE SUPPORT

a. Does your service support, irrespective of contracted service or warranty repair covers after office hours i.e. after 5.30 pm and weekends?
   - After office hours * Yes/No
   - During weekend * Yes/No
   - Labour charge for non contract service during office hour $___________/hr
   - Labour charge for non contract service after office hour $___________/hr
   - Labour charge for non contract service during weekend $___________/hr

* Please attach operating hours for service support for our information. And provide Sales and Service organisation chart for emergency contract.

b. What percentage of essential spare part support are you stocking to meet TTSH repair/service needs?
   - percentage of stock essential spare parts relative to ________ %
   - cost of stocked items $________

* Full list of essential spare parts is required. Kindly indicate those that you would be stocking. Non-stock parts would still be reflected in the full list.
   - percentage of stocked essential spare parts relative to the whole system (i.e. all the parts that make up the system) ________ %

c. Please list the TOP 5 most expensive spare part for this unit.

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<tr>
<th>Part No.</th>
<th>Description</th>
<th>Cost (SGD)</th>
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d. If parts are to be delivered from overseas, kindly state the turnaround time for delivery to TTSH
   - Standard delivery ________ days
   - Courier delivery ________ days
   - Air Parcel ________ days
iv) Others

Number of years spare part will continue to be available after the discontinuation of the model purchased by TTSH

f. Frequency of PM (times/year) during warranty period

g. 24-hours service available  * Yes/No

h. Service response time (hours)

i. Maximum down time

j. Are your Service Engineer trained on the proposed system?  * Yes/No

  - Name of trained personnel  pls specify
  - Designation  pls specify
  - Educational qualification pls specify
  - Contact No/pager for backup services  pls specify
  - Years of service with the employer
  - Factory Trained  pls specify

( If you are not factory trained, please give details of your supervisor or colleague who trained you and supervise your work.)

  - Last Training date  pls specify
  - Next Re-certification date  pls specify

k. Is replacement unit available?  * Yes/No

l. Can replacement unit be made available within 24 hours upon request during warranty period?  * Yes/No

m. Is the loaner unit available for equipment under repair after warranty period without charges?  * Yes/No

  If there is charges, what are the charges?

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Contractor Stamps and Authorised Signature
n. Spare Part list (Stocked and Non-stocked items) valid for two (2) years after warranty

<table>
<thead>
<tr>
<th>S/N</th>
<th>Description</th>
<th>Unit Price</th>
<th>Stock Item Y/N</th>
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33. TRAINING

a. Does your **In-service training** cover:

- equipment operation * Yes/No
- general maintenance * Yes/No
- equipment safety verification (for use on patients) * Yes/No
- others pls specify

b. Does your **technical training** cover:

- installation instructions * Yes/No
- system overview with block diagram * Yes/No
- detailed theory of operation * Yes/No
- detailed preventive maintenance procedures * Yes/No
- detailed calibration and performance checks * Yes/No
- detailed trouble shooting * Yes/No
- overhaul procedures * Yes/No
- others pls specify

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- Trained by Manufacturer to service product *(Pls submit certificates)*
  * Yes/No

- Certified by manufacturer to provide technical training *(Pls submit certificates)*
  * Yes/No

- Date of last technical training received for this product
  pls specify
  __________________________

### e. Training Program

<table>
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<th>S/N</th>
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<th>Duration</th>
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</table>
34. **AVAILABILITY OF EVALUATION UNIT** *Yes/No*

35. **AVAILABILITY OF SERVICE MANUALS** *Yes/No*
   (2 X CD of operating/service manual in soft copy for Biomedical Engineering)

36. **DO YOUR COMPANY OWN A ELECTRICAL SAFETY ANALYSER?** *Yes/No*
   
   If yes, please specify the Brand: ______________ & Model: ______________

37. **REFERENCES (LOCAL ONLY)**

<table>
<thead>
<tr>
<th>S/N</th>
<th>Year Purchased</th>
<th>Institution</th>
<th>Contact Person/Number</th>
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I hereby certify that all information are true and correct and shall fully comply with all requirements stated in this specifications, unless stated otherwise under the Statement of Non-compliance.

_____________________________________________________
Authorised Signature & Stamp/Seal of the Contractor

_____________________________________________________
Name/Designation/Contact No. Date

Email Address:_____________________________________________________

** Please note that full information shall be provided before the closing date. Insufficient information will not be accepted.

All information must be provided to avoid rejection of offer.

Every page of the Technical & Performance summary must be duly signed and return with the submission.
ANNEX A-1   COMPLIANCE TO REQUIREMENTS/SPECIFICATION

Please specify in the format below all areas of non-compliance. Failure to use this format may render the Tender submission liable to rejection. **KINDLY REPRODUCE ADDITIONAL COPIES AS NECESSARY.**

<table>
<thead>
<tr>
<th>Requirements/Specification Clause No.</th>
<th>Full Details of Non-Compliance</th>
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ANNEX A-2 CONTRACTOR CHECKLIST for SUBMISSION OF DOCUMENTS

1. **CONFORMITY CERTIFICATES**

   **IMPORTANT:** INDICATE “YES” ONLY WHEN DOCUMENTS ARE SUBMITTED!

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>a. IEC/EN 60601-1/ IEC 61010-1</td>
<td>* Yes/No</td>
</tr>
<tr>
<td>b. IEC/EN 61000-4-x series or equivalent EMC compliance</td>
<td>* Yes/No</td>
</tr>
<tr>
<td>c. IEC/EN 60601-1-2 or equivalent EMC compliance</td>
<td>* Yes/No</td>
</tr>
<tr>
<td>d. A copy of the HSA registration certificate of the equipment</td>
<td>* Yes/No</td>
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<tr>
<td>e. Other related</td>
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2. **FDA CLEARANCE**

<p>| | |</p>
<table>
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<tbody>
<tr>
<td>a. Pre-market notification (510K)</td>
<td>* Yes/No</td>
</tr>
<tr>
<td>b. Pre-market approval (PMA)</td>
<td>* Yes/No</td>
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3. **MANUFACTURER’S LETTER**

<p>| | |</p>
<table>
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<tbody>
<tr>
<td>a. Distributor appointment letter</td>
<td>* Yes/No</td>
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<tr>
<td>b. Frequency of preventive maintenance per year recommended by manufacturer</td>
<td>* Yes/No</td>
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</tbody>
</table>

4. **PREVENTIVE MAINTENANCE (PM)**

<p>| | |</p>
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<tbody>
<tr>
<td>a. Checklist</td>
<td>* Yes/No</td>
</tr>
<tr>
<td>b. Procedure for carrying out PM</td>
<td>* Yes/No</td>
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5. **SPARE PART PRICE LIST**

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<table>
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<tbody>
<tr>
<td>a. Full list with price valid for 2 years</td>
<td>* Yes/No</td>
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<tr>
<td>b. Stocked spare parts</td>
<td>* Yes/No</td>
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6. **TRAINING PROGRAMME**

<p>| | |</p>
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<tbody>
<tr>
<td>a. Detailed Technical training indicating the number of days and the time required for each segment of the training.</td>
<td>* Yes/No</td>
</tr>
<tr>
<td>b. Operator</td>
<td>* Yes/No</td>
</tr>
</tbody>
</table>
7. **REFERENCE LIST**

   a. Telephone no/contact person  * Yes/No

   b. Year in which they were supplied


8. **PERFORMANCE SUMMARY**

   a. Fully completed  * Yes/No

   *(Performance summary is INCOMPLETE without the SUBMISSION of documents!)*

9. **ORGANISATION CHART**  * Yes/No

10. **CERTIFICATES OF TECHNICAL SERVICE ENGINEERS**  * Yes/No

11. **OTHERS**

   __________________________________________________________________________________

   __________________________________________________________________________________