TENDER AMENDMENT

Reference Tender Notice No: NEIGR/S&P/03/05/2018-2019; Dated: 17.05.2018 pertaining to Tender Enquiry No: NEIGR/S&P/OT/E-08/2018 -19 for processing of Laboratory Refrigerator, Table Top Centrifuge, Air Sampler, Autoclave, Incubator, Plasma Sterilizer for Infection Control -Targetted Surveillance, for implementation of project under Swachhta Action Plan in the Institute

Kindly note the following item along with the specification in sequential order:-

**Section – VII**  
Technical Specifications:

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Name of the Equipment</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Autoclave</td>
<td>02 nos</td>
</tr>
<tr>
<td></td>
<td>- As the specification of the Autoclave has indicated two inner chambers (i.e. 400 x 600 MM and 300 x 300 MM), Bidders are to offer the rate of 400 x 600 MM chamber in the BOQ (e-Price bid) and size 300 x 300 MM in the technical bid, as percentage of FOB /Ex-factory price of Sl. No. 1.01.</td>
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<tr>
<td>2.</td>
<td>Table Top Centrifuge</td>
<td>02 nos</td>
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<tr>
<td>3.</td>
<td>Automated Microbiological Air Sampler</td>
<td>01 no</td>
</tr>
<tr>
<td>4.</td>
<td>Microbiological Incubator</td>
<td>01 no</td>
</tr>
<tr>
<td>5.</td>
<td>Plasma Sterilizer</td>
<td>01 no</td>
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<td></td>
<td><strong>Note:</strong> Cost of Reagents /Consumables @ 500 cycles per year should be quoted in the techno-commercial bid, as percentage of FOB /Basic Price, which will be taken for the purpose of price evaluation and the rates should be valid for a period of ten years.</td>
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<tr>
<td>6.</td>
<td>Laboratory Refrigerator</td>
<td>02 nos</td>
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</table>

**Please Note:**
- As the specification of the Autoclave has indicated two inner chambers (i.e. 400 x 600 MM and 300 x 300 MM), Bidders are to offer the rate of 400 x 600 MM chamber in the BOQ (e-Price bid) and size 300 x 300 MM in the technical bid, as percentage of FOB /Ex-factory price of Sl. No. 1.01.

**Detailed Specification:** (See below)
AUTOCLAVE

1. Microprocessor based electrically heated vertical steam sterilizer.
2. Pressure range 15-20 psig adjustable, pressure control switch with digital display.
3. Outer and inner chamber made of Stainless Steel.
4. Inner chamber made of at least 18 SWG SS sheet.
5. Inner chamber size 400 x 600MM (big) and 300x300MM (small).
6. Stainless Steel steam jacket insulated with high grade glass wool, water level indicator with automatic low water level cutoff device, joint less gasket, water inlet and drain valves, with standard safety features.

Environmental factors:
2. The unit shall be capable of being stored continuously in ambient temperature of 0-50deg C and relative humidity of 15-85%.
3. The unit shall be capable of operating in ambient temperature of 20-30 deg C and relative humidity of 80%.

Power Supply:
1. Power input to be 220-240VAC, 50Hz. supplied with standard accessories including one pair of gasket and heating coil.
2. Suitable voltage stabilizer of 2kV.
3. Suitable Auto voltage corrector with spike protector should be available.
4. Rechargeable source battery shall be fitted for protection.

Standards and Safety:
1. Should be FDA or CE or ISI approved product.
2. Electrical safety conforms to standards for electrical safety IEC-60601 /IS-13450.
3. Should be compliant to ISO 13485 : Quality systems – Medical devices – Particular requirements for the application of ISO 9001 applicable to manufacturer and service providers that perform their own design activities.
4. Calibration according to NIST/DKDP-2/UKAS/NI/IL/C1/L, listed.
5. Five (5) years warranty from the date of installation and thereafter Five (5) years CMC.

Documentation:
1. User/Technical/Maintenance manual to be supplied.
2. List of Equipment available for providing calibration and routine maintenance support as per manufacturer documentation in service / technical manual.
3. Log book with instruction for daily, weekly, monthly and quarterly maintenance checklist. The job description of the hospital technician and accompany service engineer should be clearly spelt out.

A. C. Phukan
HOD Microbiology
NEIGRIHMS, Shillong
Table Ten Centrifuge

Automatic processor controlled, swing out rotor

Maximum speed: 10,000 rpm

The Centrifuge must be capable of generating RCF is excess to 2000xg.

Should be able to accommodate to spin 8 tubes 13 x 75 mm or 13 x 180 mm at a time. There should be provision of accessories of angle head rotor for 2 ml and 0.5 ml tube.

The system should have brushless induction drive,

Dynamic braking for rapid stop with out cell disturbance. System should have safety features like lid lock and lid interlock. System should have touch keypad for date entry and large LED display for good visibility with provision of timer (0-90 minutes). Noise level should be less than 60 db. Electrical 220 volts 50 Hz.

CE, ISO 9001, ISO13485 Marked or equivalent marked.

There should be technical support and after sale engineering service provision from the Responders. It is necessary to furnish the Users' list to Government set-ups, especially in the North-East region of India. Certificate of proven satisfactory performance is to be accompanied along with terms & conditions and service agreement of the Responders.

Power Supply:
1. Power input to be 220-240VAC, 50Hz. supplied with standard accessories including one pair of gasket and heating cell.
2. Suitable voltage stabilizer of 2KV.
3. Suitable Auto voltage corrector with spike protector should be available.
4. Resettable overcurrent breaker shall be fitted for protection.

Standards and Safety:
1. Should be FDA or CE or ISI approved product.
2. Electrical safety conforms to standards for electrical safety IEC-60601 / IS-13450.
3. Should be compliant to ISO 13485: Quality systems – Medical devices – Particular requirements for the application of ISO 9001 applicable to manufacturers and service providers that perform their own design activities.
4. Calibration according to NIST/DEP/TPL/AKAS/NPL/LUL/CUL listed.
5. Five (5) years warranty from the date of installation and thereafter Five (5) years CMC.

Documentation:
1. User/Technical/Maintenance manuals to be supplied.
2. List of Equipment available for providing calibration and routine maintenance support as per manufacturer documentation in service/technical manual.
3. Log book with instructions for daily, weekly, monthly and quarterly maintenance checklist. The job description of the hospital technician and accompany service engineer should be clearly spelt out.

A. C. Phukan
HOD Microbiology
NEIGRIHMS, Shillong
Automated Microbiological Air Sampler

Easy-to-Use
1. It should be intuitive use with light weight and easy-to-transport
2. Remote control function should be available
3. It should use standard Peltier plates.

Accurate & Reproducible
1. Electronic speed and flow rate control
2. Battery load indicator with safety check

Robust
1. Stainless steel sampling grid should be steam sterilizable
2. Grid should be resistant to disinfectants
3. Sampling volume should be adjustable
4. Delayed start should be adjustable from 1 s to 60 min
5. Remote control of several sample air units simultaneously should be possible
6. Alphanumeric display of messages and parameters should be available

Validated Performance
1. The system performance should be according to ISO 16698-2
2. Collection efficiency of microorganisms should be over 99%
3. Collection of microorganisms with particle size as low as 0.8 μm should be possible
4. The system should include traceability functions and PC/Printer connection

Environmental factors
1. Shall meet IEC-60601-2-2001 (or Equivalent BIS), General Requirements of Safety for Electromagnetic Compatibility
2. The unit shall be capable of being stored continuously in ambient temperature of 0-50deg C and relative humidity of 15-90%
3. The unit shall be capable of operating in ambient temperature of 20-30 deg C and relative humidity of 80%

Power Supply
1. Power input to be 220-240VAC, 50Hz, supplied with standard accessories including one pair of gasket and heating cell
2. Suitable voltage stabilizer of 2kV
3. Suitable Auto voltage corrector with spike protector should be available
4. Resettable overcurrent breaker shall be fitted for protection

Standards and Safety
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2. Electrical safety conforms to standards for electrical safety IEC-60601 / IS-13485
3. Should be compliant to ISO 13485: Quality systems – Medical devices – Particular requirements for the application of ISO 9001 applicable to manufacturers and service providers that perform their own design activities
4. Calibration according to NIST/DEK/PTB/UKAS/NF/UL/CUL listed
5. Five (5) years warranty from the date of installation and thereafter Five (5) years CMC

Documentation
1. User/Technical/Maintenance manuals to be supplied
2. List of Equipment available for providing calibration and routine maintenance support as per manufacturer documentation in service/technical manual

Log book with instruction for daily, weekly, monthly and quarterly maintenance checklist. The job description of the hospital technician and accompanying service engineer should be clearly spelt out.
Microbiological Incubator

Microprocessor controlled temperature. The system should have a temperature control range from Ambient ±5°C to 40°C. The heat transfer to environment at 37°C should be 40 W/h. The equipment should have inner chamber Volume of 60-800 ltrs. The system should have a temperature deviation of ± 0.2°C at 37°C. The system should have heating up time of less than 45 min to achieve 37°C. The equipment should have a temperature recovery time of 10 min. at 37°C. The equipment should have rounded edges and corners for easy cleaning. Equipment should have interface for documentation of temperature during incubation.

CE, ISO 9001, ISO 13485 Marked or equivalent marked.

Power Supply:
1. Power input to be 220-240VAC, 50Hz supplied with standard accessories including one pair of gasket and heating cell.
2. Suitable voltage stabilizer of 2KV.
3. Suitable auto voltage corrector with spike protector should be available.
4. Resettable overcurrent breaker shall be fitted for protection.

Standards and Safety:
1. Should be FDA or CE or ISI approved product.
2. Electrical safety conforms to standards for electrical safety IEC-60601 / IS-13450.
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Documentation:
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Log book with instruction for daily, weekly, monthly and quarterly maintenance checklist. The job description of the hospital technician and accompanying service engineer should be clearly spelt out.

[Signature]
A. C. Phukan

HOD Microbiology

NIHUIMS, Shillong
<table>
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<tr>
<th>Plasma Sterilizer</th>
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<tbody>
<tr>
<td>1. The unit should be the fully micropressure controlled plasma sterilizer.</td>
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<tr>
<td>2. The unit should be kept on the four legs standing with middle wheels and four loading top.</td>
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<td>3. The standard /normal cycle should be less than 32 minutes and advanced cycle should be less than 40 minutes. The cycle program should be automatically performed.</td>
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<td>4. The unit should sterilize surgical instruments using state of the art oxygen peroxide/autoclave technology.</td>
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<td>5. The temperature of sterilization should be in the range of 95 degree Celsius and low moisture.</td>
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<td>6. Should describe rough pan during cycle.</td>
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<tr>
<td>7. The unit should have at least 15 mm. inner diameter for thorough and the chamber should be in circle.</td>
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<td>8. Should be delete similar flexible as well as rigid endoscope.</td>
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<tr>
<td>9. Sterilize skin in multiple steps through 100° C巴斯洛 type Transmission 100°C.</td>
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<tr>
<td>10. The sterilizing agent (peracetic acid) should be in a closed vessel or chamber for perfect dispensing, accurate and better sterility assurance.</td>
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<tr>
<td>11. The unit should have release residues with primary by-products being water vapour and oxygen and it should be safe for patient, staff and environment.</td>
</tr>
<tr>
<td>12. The unit should completely and automatically monitor the operation and reporting with auxiliary alarms and tests on thermal printer.</td>
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<tr>
<td>13. The operation of the sterilizer should have no requirement of additional water supply source.</td>
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<td>14. The resistance to rust should be amenable maintenance at factory or easy maintaining activity.</td>
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<tr>
<td>15. Sterilization chamber is made of stainless steel AISI 316L.</td>
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<td>16. Should start the sterilization data by micro card.</td>
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<td>17. Equipment function should be supported for 220V-50/60 Hz single phase.</td>
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<td>18. Plasma sterilizer should contain the following forms and directions:</td>
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<tr>
<td>- ISO 12183-2000 Quality systems</td>
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<td>- ISO 12185:2006 Quality system for medical devices</td>
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<tr>
<td>- ISO 14150-2001 all requirements for sterilization of medical products</td>
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<td>- (Normative 9148/2012)</td>
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<tr>
<td>19. The plasma sterilizers should be of high quality with European/US FDA approved.</td>
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<tr>
<td>20. The unit should be supplied with 172 pounds net metering multiple sterilization trays.</td>
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<tr>
<td>21. The sterilizer should be supplied with sterilization compartments, sterilization marker, sterilization check palette, load palette for packing and paper roll to run at least 150 cycles.</td>
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</tbody>
</table>
All other terms and conditions remain the same.

For further details regarding amendment, addendum, extension and downloading of documents, please visit website: www.eprocure.gov.in /www.neigrihms.gov.in; Tel/Fax: 0364-2538032; E-mail: storeneigrihms@gmail.com.

Sd/-
Stores & Procurement Officer,
For and on behalf of Director, NEIGRIHMS