

**All Bidders****Amendment-IV**

Subject: Execution including Supply, Installation, Testing & Commissioning of CSSD for Advanced Neuro Science Centre at PGIMER, Chandigarh

Tender No: HSCC/SES/CSSD/PGI/Neuro Science/2023 Date: 02.02.2023

This has reference to above tender.

The following Amendment may be noted which shall be treated as part of the tender document and to be submitted duly signed & stamp along with tender.

Sr. No.	Bidder's Queries	Reply
1.	<b>Period of Completion</b> of this project estimated to be 4 months is too short, it should be at least <b>6months</b> from the date of notification of award and hand over of the site if the turnkey job is not removed out of the scope of the works. Because the international deliveries are not less than 90 days and ship sailing time of 45 days, customs Clearance of 4 days, inland transit & unloading etc. of 2 days, installation of 30 days, testing of 7 days itself totals to 178 days and none of these can be cut down except trying with the manufacturer to some extent. All good international companies have a healthy orderbook, and these are all customs made products configured to the client's specifications.	Tender terms & conditions prevail.
2.	<b>Estimated budget</b> is too little for the specifications proposed. Please bear in mind that both the US\$ and EURO have appreciated vis-à-vis Indian Rupee by more than 10%, freight services have gone up by 15 ~ 20 % and all of these have an impact on Customs Duty payable. Added to these, the manufacturer's prices have gone up w.e.f. 1.1.2023 again by 15 ~ 20 % due to steel, electronics components etc. It is therefore requested that the budget may be enhanced by 25% at least.	Tender terms & conditions prevail.
3.	<b>Manufacturer's Authorisation</b> should be restricted to only the main items like Steam Sterilizers and Washer Disinfector. All other 3rd party items such as but not limited to Plasma Steriliser, table top sterilizer, Ultrasonic, furniture,	Tender terms & conditions prevail.

	utilities etc should be exempted out of this.	
4.	MII clause if any must be dispensed away as majority of the items are NOT made in India for the specifications laid out. Only local furniture and services are possible from Indian vendors.	Tender terms & conditions prevail.
5.	<p>Pre-Qualification Criterion should be changed to allow bidders who have the competency of maintaining these equipment and NOT prior experience of their non core competencies e.g. turnkey jobs. Our logical submission in this regards are :</p> <p><b>a)</b> You have carefully selected a vendor M/s Deepak Builders and Engineers (India) Limited to erect the mammoth building of advanced Neurosciences Centre, why should they not undertake the services like civil, electrical, Interior, fire fighting system, water, plumbing, air-conditioning, CCTV etc. for better control and costs.</p> <p><b>b)</b> We can assist in making the layout of the CSSD with our expertise and monitor the progress with PGIMER staff for the progress of the work every 15 days or required intervals FREE of CHARGE, if we are awarded the contract of supply, installation, and maintenance of the CSSD equipment.</p> <p><b>c)</b> We have executed one of the largest CSSD under one hospital roof at Maa Amrita Institute of Medical Sciences at Faridabad with Belimed Switzerland equipment. The order value of the equipment alone was more than 5 crores. However, the contract was between Belimed and AMRITA. Therefore, our company's name is not appearing on their contract and that contract is highly confidential and is not accessible to us.</p> <p>We entered into a contract for installation, maintenance with the manufacturer for a fee and have completed all the installation by our team and the visiting team from the manufacturer's side. Our engineers are well trained to handle the upkeep of the equipment.</p> <p>We have been also awarded a contract worth more than 5 crores for the supply, installation, and maintenance of CSSD equipment alone to all hospitals of the Indian Army with washer disinfectors and the project is being executed, where all supplies have been made and client's sites are not ready and / or getting ready.</p>	Tender terms & conditions prevail.

	<p>d) From the above submissions, it is clearly established that we are not novice in the CSSD arena and possess the capability to render the required MAIN job of planning, installation, and maintenance of the CSSD equipment.</p> <p>e) It may be prudent to have ONE and SAME supplier for the whole centre at PGIMER for common services such as AC, Fire Fighting etc</p> <p>f) Therefore, please either delete the Turnkey work from the scope of the work or <b>allow consortium bids where we can either engage the same contractor</b> or any other qualified contractor(s) to make a combined bidding with responsibility resting with us.</p>	
6.	We have visited the site and have been informed that the proposed location is Basement 1, but the exact area and drawing has not been handed over.	Tender terms & conditions prevail.
7.	If all submissions are agreed to, then we can bid with world class products (BELIMED) and would request you to arrange to grant at least 25 days' time to prepare the bids.	Tender terms & conditions prevail.
8.	<p>Technical changes Requested are:</p> <p>a) 1000 L capacity may be amended to read as 12 STU or better 15 STU like for sr. no 2 , you have specified 4 STU.</p> <p>b) BOWIE Dick Test must be integrated to not only save costs but to keep electronic records of the quality tests for future audits and remotely activating to save cycle times.</p> <p>c) Water is a scarce and important resource, and the specifications should insist for lowest water consumption and total water used in 10,000 cycles @ Rs. 10/litre (or as decided by your institute)will be added before arriving at the lowest bidder.</p> <p>d) Sr. no. 4 double door washers should be changed to fix one DIN tray capacity say 18 or better would be to have 2 X 10 DIN trays ( for backup in case one breaks down and/or warranty service time ). Leaving it vague 12~15 MEANS 12 ONLY. Between 2 sterilizers, we feel one 12 DIN tray Washer would be inadequate.</p> <p>e) The lay out and scope of work must keep provision of future expansions like addition of one more washer or one more sterilizer etc.</p> <p>f) Sr no. 5 Plasma sterilizer to be amended to 110 L or more (instead of 120 ~ 150 )</p>	Tender terms & conditions prevail.
9.	Third Party Certification should be exempted as all major items will be CE(EU) certified final	Tender terms & conditions

	payments are linked with functional testing.	prevail.
10.	Payment terms are not clear from the tender documents.	Tender terms & conditions prevail.
11.	<p><b>Technical Specification</b>  <b>Item No. 1 Horizontal Sterilizer 1000L Capacity and accessories</b></p> <p><b>Page No. 3, Point (n)</b>  Directives &amp; Standards: It should meet EN ISO / IEC/BIS directives and product should be BIS/European CE/ US FDA Standards. Copy of certificate is to be attached. (o) Should pass a hollow load (A) test (Batch monitoring system).</p> <p>Amendment Request:</p> <p>Directives &amp; Standards: It should meet EN ISO / IEC/BIS directives and product should be <b>European CE from notified body with 4 digit no.</b> / US FDA Standards. Copy of certificate is to be attached. (o) Should pass a hollow load (A) test (Batch monitoring system).</p> <p>Having examined the tender documents, it is found that complete technical specification of the products are imported, hence BIS standard is not required for the same, Kindly deleted the same.</p> <p>Kindly amend European CE from notified body with 4 digit no. for better productivity of the product.</p>	Tender terms & conditions prevail.
12.	<p><b>Item No. 2 Sterilizer 250 liters with minimum 4 STU capacity with Accessories:</b></p> <p><b>Page no. 6, Point (n)</b>  It should be BIS/USFDA/ European CE</p> <p>Amendment Request:</p> <p>It should be USFDA/ <b>European CE from notified body with 4 digit no.</b></p> <p>Having examined the tender documents, it is found that complete technical specification of the products are imported, hence BIS standard is not required for the same, Kindly deleted the same.</p>	Tender terms & conditions prevail.

	<p>Kindly amend European CE from notified body with 4 digit no. for better productivity of the product.</p>	
<p>13.</p>	<p><b>Item No. 3 Rapid Sterilizer (Flash Autoclave) Table Top Sterilizer with Accessories for TSSU</b></p> <p><b>Page No. 6, Point no. 5</b> Sterilizer should be BIS/US FDA/ European CE Certified.</p> <p>Amendment Request:</p> <p>Sterilizer should be BIS/US FDA/ <b>European CE from notified body with 4 digit no.</b></p> <p>Having examined the tender documents, it is found that complete technical specification of the products are imported, hence BIS standard is not required for the same, Kindly deleted the same.</p> <p>Kindly amend European CE from notified body with 4 digit no. for better productivity of the product.</p>	<p>Tender terms &amp; conditions prevail.</p>
<p>14.</p>	<p><b>Item No. 3 Rapid Sterilizer (Flash Autoclave) Table Top Sterilizer with Accessories for TSSU</b></p> <p>Control Panel: The control system should be microprocessor based PLC system specially designed for sterilization applications. The control system should have CPU processor with battery back-up, Digital input/output controls, analogue measuring inputs &amp; COM ports for printer &amp; PC connectivity.</p> <p>Amendment Request:</p> <p>Control Panel: The control system should be microprocessor based PLC system specially designed for sterilization applications. The control system should have CPU processor with battery back-up, Digital input/output controls, analogue measuring inputs &amp; COM ports for printer.</p> <p>Having examined the tender documents, it is found that complete technical specification of the products on based on PC Connectivity which is not required for the same, Kindly deleted the same.</p>	<p>Tender terms &amp; conditions prevail.</p>

	Kindly amend the point as requested.	
15.	<p><b>Item No. 4 Double Door Washer Disinfector 280-350 Litre (12-15 DIN Tray) with Accessories</b></p> <p><b>Page No. 8, Point No. 8</b></p> <p>The device should be a medical device according to Directive 93/42 EEC concerning medical devices. Should be BIS/US FDA/European CE certified.</p> <p>Amendment Request:</p> <p>The device should be a medical device according to Directive 93/42 EEC concerning medical devices. Should be US FDA/ <b>European CE from notified body with 4 digit no.</b></p> <p>Having examined the tender documents, it is found that complete technical specification of the products are imported, hence BIS standard is not required for the same, Kindly deleted the same.</p> <p>Kindly amend European CE from notified body with 4 digit no. for better productivity of the product</p>	Tender terms & conditions prevail.
16.	<p><b>Item No. 5 Plazma Sterilizer (Double door) 120-150 L</b></p> <p><b>Page No. 9, Point no. 14</b></p> <p>Should quote same make consumables having EPA-US/ European CE/BIS</p> <p>Amendment Request:</p> <p>Should quote same make consumables having EPA-US/ <b>European CE from notified body with 4 digit no.</b></p> <p>Having examined the tender documents, it is found that complete technical specification of the products are imported, hence BIS standard is not required for the same, Kindly deleted the same.</p> <p>Kindly amend European CE from notified body with 4 digit no. for better productivity of the product.</p>	Tender terms & conditions prevail.

17.	<p><b>Item No. 6 Ultrasonic Cleaner (40L)</b></p> <p><b>Page No. 9 Point (a)</b>  The units should be a compact free-standing bench model, with a built-in tank manufactured from high-quality (SS-316) stainless steel and a solid-state generator that sends ultrasonic (approx 40 KHz) impulses through wash water containing detergent and electrical heating; microprocessor controlled display with memory time and temperature functions.</p> <p>Amendment Request:</p> <p>The units should be a compact free-standing bench model, with a built-in tank manufactured from high-quality (SS-316) stainless steel and a solid-state generator that sends ultrasonic (approx 40 KHz) impulses through wash water containing detergent and electrical heating.</p> <p>Every manufacturer have their own model with different features, hence every manufacturer will offer relevant/suitable model with their features, as technical specification of the tender.</p> <p>Kindly amend the point as requested.</p>	Tender terms & conditions prevail.
18.	<p><b>Item No. 6 Ultrasonic Cleaner (40L)</b></p> <p><b>Page No. 9 Point No. (h)</b>  Ultrasonic cleaner should be BIS/European CE/USFDA Certified.</p> <p>Amendment Request:</p> <p>Ultrasonic cleaner should be <b>European CE from notified body with 4 digit no.</b> /USFDA Certified.</p> <p>Having examined the tender documents, it is found that complete technical specification of the products are imported, hence BIS standard is not required for the same, Kindly deleted the same.</p> <p>Kindly amend European CE from notified body with 4 digit no. for better productivity of the product</p>	Tender terms & conditions prevail.
19.	<p><b>Item No. 7 Heat Sealing Machine</b></p> <p><b>Page No. 10, Point no. 14</b></p>	Tender terms & conditions prevail.

	<p>It should be BIS/European CE/US FDA Certified.</p> <p>Amendment Request:</p> <p>It should be <b>European CE from notified body with 4 digit no.</b> /US FDA Certified.</p> <p>Having examined the tender documents, it is found that complete technical specification of the products are imported, hence BIS standard is not required for the same, Kindly deleted the same.</p> <p>Kindly amend European CE from notified body with 4 digit no. for better productivity of the product</p>	
20.	<p>Vol04_TechSpecs &gt; Pg. 1 1. HORIZONTAL STERILIZER 1000L CAPACITY AND ACCESSORIES</p> <p>Please amend this to a range of 850-1000L for wider participation.</p>	Tender terms & conditions prevail.
21.	<p>Vol04_TechSpecs &gt; Pg. 1 1. HORIZONTAL STERILIZER 1000L CAPACITY AND ACCESSORIES</p> <p>The chamber should be jacketed to ensure the temperature uniformity in chamber with multiple heaters. Specify the number of heaters.</p> <p>There is no requirement of heaters in the chamber as temperature uniformity can be achieved naturally by the heating jacket. Heaters are only available in the steam generator.</p>	Tender terms & conditions prevail.
22.	<p>Vol04_TechSpecs &gt; Pg. 3 1. HORIZONTAL STERILIZER 1000L CAPACITY AND ACCESSORIES</p> <p>Cycle Documentation – Printer: The autoclave should be equipped with an alpha-numeric Laser/thermal printer which prints each cycle parameter performed by the sterilizer</p> <p>Please amend this to:</p> <p>Cycle Documentation – Printer: The autoclave</p>	Tender terms & conditions prevail.



	<p>should be equipped with an alpha-numeric Laser/thermal printer/DOT Matrix which prints each cycle parameter performed by the sterilizer. Prints from laser/thermal printers fade over a period, which is detrimental for record-keeping.</p>	
23.	<p>Vol04_TechSpecs &gt; Pg. 4 2. STERILIZER 250 Litres and with minimum 4 STU capacity with</p> <p>Accessories: The chamber should be jacketed to ensure the temperature uniformity in chamber with multiple heaters. Specify the number of heaters.</p> <p>There is no requirement of heaters in the chamber as temperature uniformity can be achieved naturally by the heating jacket. Heaters are only available in the steam generator.</p>	Tender terms & conditions prevail.
24.	<p>Vol04_TechSpecs &gt; Pg. 6 2. STERILIZER 250 Litres and with minimum 4 STU capacity with</p> <p>Accessories: Cycle Documentation – Printer: The autoclave should be equipped with an alpha-numeric Laser/thermal printer which prints each cycle parameter performed by the sterilizer</p> <p>Please amend this to: Cycle Documentation – Printer: The autoclave should be equipped with an alpha-numeric Laser/thermal printer/DOT Matrix which prints each cycle parameter performed by the sterilizer. Prints from laser/thermal printers fade over a period, which is detrimental for record-keeping.</p>	Tender terms & conditions prevail.
25.	<p>Vol04_TechSpecs &gt; Pg. 7 4. DOUBLE DOOR WASHER DISINFECTOR 280-350 Litre (12-15 DIN Trays) WITH ACCESSORIES</p> <p>Please amend to “DOUBLE DOOR WASHER DISINFECTOR 275-350 Litre (10-12 DIN Trays) WITH ACCESSORIES” OR “DOUBLE DOOR WASHER DISINFECTOR 280-400 Litre (15-18 DIN Trays) WITH ACCESSORIES” for wider participation. 12 DIN to 15 DIN in manufacturer-</p>	Tender terms & conditions prevail.

	specific and should be amended for encouraging competition.	
26.	<p>Vol04_TechSpecs &gt; Pg. 7  4. DOUBLE DOOR WASHER DISINFECTOR 280-350 Litre (12-15 DIN Trays) WITH ACCESSORIES</p> <p>d. Chamber capacity: Operational Volume should be able to process minimum 12 DIN trays (Approx480X250X50) to 15 Trays with 6 levels in single process. Should supply 12 -15 Nos of standard Stainless Steel DIN trays. The chamber should be made of S.S. 316L quality with electro polished washed surfaces</p> <p>Please amend this to:  “d. Chamber capacity: Operational Volume should be able to process minimum 10 DIN trays (Approx480X250X50) to 12 Trays with 5-6 levels in single process. Should supply 10 – 12 Nos of standard Stainless Steel DIN trays. The chamber should be made of S.S. 316L quality with electro polished washed surfaces”</p> <p>OR  “d. Chamber capacity: Operational Volume should be able to process minimum 15 DIN trays (Approx480X250X50) to 18 Trays with 5-6 levels in single process. Should supply 15 - 18 Nos of standard Stainless Steel DIN trays. The chamber should be made of S.S. 316L quality with electro polished washed surfaces”</p> <p>This must be amended for wider participation. 12 DIN to 15 DIN is manufacturer-specific and should be amended for encouraging competition.</p>	Tender terms & conditions prevail.
27.	<p>Vol04_TechSpecs &gt; Pg. 8  5. PLASMA STRILIZER (Double door)-120-150 L (Material SS-316/SS-316L)</p> <p>Please amend this to:  5. PLASMA STERILIZER (Double door)-120-150 L (Material SS-316/SS-316L/Aluminum). There is no requirement of SS in Plasma Sterilizer because there is no aqueous process involved. Entire process is achieved by Hydrogen Peroxide.</p>	Tender terms & conditions prevail.
28.	<p>Vol04_TechSpecs &gt; Pg. 9  5. PLASMA STRILIZER (Double door)-</p>	Tender terms & conditions

	<p>120-150 L (Material SS-316/SS-316L) Usable Rectangular chamber having volume of minimum 120L-150 litres.</p> <p>Please amend this to: “Usable Rectangular chamber having volume of minimum 100L-150 litres.” for wider participation and encouraging maximum bidders to participate in the tender.</p>	prevail.
29.	<p>Vol04_TechSpecs &gt; Pg. 9 5. PLASMA STRILIZER (Double door)- 120-150 L (Material SS-316/SS-316L)</p> <p>Should be environment friendly and have no toxic by-products or harmful residues and should approval of EPA to guarantee its non-harmful feature.</p> <p>EPA is an American agency. European manufacturers do not meet this requirement. This specification restricts competition and should be omitted from tender.</p>	Tender terms & conditions prevail.
30.	<p>Vol04_TechSpecs &gt; Pg. 9 6. ULTRASONIC CLEANER (40 L) h. Ultrasonic cleaner should be BIS/European CE /US FDA certified.</p> <p>Please amend this to:</p> <p>h. Ultrasonic cleaner should be BIS/European CE /US FDA certified/EC Declaration of Conformity from Manufacturer Please be informed that Ultrasonic Cleaner is not considered a medical device under Class 1, Class 2, or Class 3 device category as per medical device directives.</p> <p>Majority of manufacturers only provide EC Declaration of Conformity. Please amend this for wider participation and encouraging competition in the tender.</p>	Tender terms & conditions prevail.
31.	<p>Vol04_TechSpecs &gt; Pg. 10 7. HEAT SEALING MACHINE 14. It should be BIS/European CE /US FDA certified</p> <p>Please amend this to:</p>	Tender terms & conditions prevail.

	<p>14. It should be BIS/European CE /US FDA certified/EC Declaration of Conformity from Manufacturer Please be informed that Heat Sealing machine is not considered a medical device under Class 1, Class 2, or Class 3 device category as per medical device directives. Majority of manufacturers only provide EC Declaration of Conformity. Please amend this for wider participation and encouraging competition in the tender.</p>	
<p>32.</p>	<p><b>Item No. 1</b></p> <p><b>HORIZONTAL STERILIZER 1000L CAPACITY AND ACCESSORIES</b></p> <p>Amendment Request:</p> <ol style="list-style-type: none"> <li><b>HORIZONTAL STERILIZER approx. 900 L or more CAPACITY with minimum 12 STU IN SINGLE PROCESS AND ACCESSORIES</b></li> </ol> <p>We would like to mention that in the international market manufacturers are making sterilizers with capacity in STU only and that is standardize and recommended for the autoclaves. STU is directly related to the load capacity which is going to be sterilized and the capacity of system having 12 STU is approx. 900- 1000 liters. <b>Hence it is requested that STU capacity must be specified.</b> Also you have specified the capacity in STU for 250 L steam Sterilizer. Hence we request your kind authority to kindly amend the points accordingly for wider &amp; healthy competition</p>	<p>Tender terms &amp; conditions prevail.</p>
<p>33.</p>	<p><b>Item No. 1</b></p> <p>Surface Treatment: The internal surface should be electro-chemically treated or mechanically treated for high quality smooth finish to facilitate cleaning. The resultant surface should be polished to less than 0.8 µm fineness to protect against corrosion. The internal corners should be rounded off to facilitate efficient cleaning.</p> <p>Amendment Request:</p> <ol style="list-style-type: none"> <li>Surface Treatment:</li> </ol>	<p>Tender terms &amp; conditions prevail.</p>

	<p>The internal surface should be electro-chemically treated or mechanically treated for high quality smooth finish to facilitate cleaning. The resultant surface should be polished to <b>1.25 µm or less</b> fineness to protect against corrosion. The internal corners should be rounded off to facilitate efficient cleaning.</p> <p>Since you have allowed 1.25 µm surface polished, so the same may please be allowed here also to enable healthy &amp; wider participation.</p>	
34.	<p>Item No. 1</p> <p>Jacket: The jacket should be made of SS-316L quality stainless steel with pressure gauge.</p> <p>Amendment Request:</p> <p>Jacket: The jacket should be made of SS-316L quality stainless steel with <b>pressure gauge/ digital display of jacket pressure.</b></p> <p>Please amend the point as requested since the same is already allowed for 250 ltrs steam sterilizer.</p>	Tender terms & conditions prevail.
35.	<p>Item No. 1</p> <p>Primary piping &amp; fittings should be stainless steel tri-clamp fittings.</p> <p>Amendment Request:</p> <p>Primary piping &amp; fittings should be <b>stainless steel tri-clamp fittings or threaded fittings</b></p>	Tender terms & conditions prevail.
36.	<p>Item No. 1</p> <p>Air Filter: Air filter should be provided for filtering the atmospheric air before entering inside the chamber. The filter separation efficiency should be higher than 99.998% for particle size less than 0.3µm. Air filter should be covered under Warranty and CMC period</p> <p>Amendment Request:</p> <p>Air Filter: Air filter should be provided for filtering the atmospheric air before entering inside the</p>	Tender terms & conditions prevail.

	<p>chamber. The filter separation efficiency should be higher than 99.998% for particle size less than 0.3µm.</p> <p>We wish to mention that the Air filter is a consumable item and has limited life which depends upon on the usage / time period. So the same should be excluded from the warranty &amp; CMC.</p>	
37.	<p>Item No. 1</p> <p>Directives &amp; Standards: It should meet EN ISO / IEC/BIS directives and product should be BIS/European CE/ US FDA Standards. Copy of certificate is to be attached. (o) Should pass a hollow load (A) test (Batch monitoring system).</p> <p>Amendment Request:</p> <p>Directives &amp; Standards: It should meet EN ISO / IEC/BIS directives and product should be <b>BIS/European CE from 4 digit notified body/</b> US FDA Standards. Copy of certificate is to be attached. (o) Should pass a hollow load (A) test (Batch monitoring system).</p>	Tender terms & conditions prevail.
38.	<p><b>Item No. 2</b></p> <p><b>STERILIZER 250 Litres and with minimum 4 STU capacity with Accessories</b></p> <p>Primary piping &amp; fittings should be stainless steel tri-clamp fittings.</p> <p>Amendment Request:</p> <p>Primary piping &amp; fittings should be <b>stainless steel tri-clamp fittings or threaded fittings</b></p>	Tender terms & conditions prevail.
39.	<p>Item No. 2</p> <p>Air Filter: Air filter should be provided for filtering the atmospheric air before entering inside the chamber. The filter separation efficiency should be higher than 99.998% for particle size less than 0.3µm. Air filter should be covered under Warranty and CMC period</p> <p>Amendment Request:</p> <p>Air Filter: Air filter should be provided for filtering</p>	Tender terms & conditions prevail.

	<p>the atmospheric air before entering inside the chamber. The filter separation efficiency should be higher than 99.998% for particle size less than 0.3µm.</p> <p>We wish to mention that the Air filter is a consumable item and has limited life which depends upon on the usage / time period. So the same should be excluded from the warranty &amp; CMC.</p>	
40.	<p>Item No. 2</p> <p>It should be BIS/USFDA/European CE</p> <p>Amendment Request:</p> <p>It should be BIS/USFDA/<b>European CE from 4 digit notified body</b></p>	Tender terms & conditions prevail.
41.	<p><b>Item No. 3</b></p> <p><b>RAPID STERILIZER (FLASH AUTOCLAVE) TABLE TOP STERILIZER WITH ACCESSORIES FOR TSSU</b></p> <p>Sterilizer should be BIS/US FDA/European CE certified</p> <p>Amendment Request:</p> <p>Sterilizer should be BIS/US FDA/<b>European CE from 4 digit notified body</b></p> <p>As four digit notified bodies are the bodies which are listed in European Union authorized list to issue European CE Certificates and thus it guarantee for a genuine product of international quality and all standard followed by the company during manufacturing/ production.</p>	Tender terms & conditions prevail.
42.	<p>Item No. 3</p> <p>Types of Cycles Process: Table Top Sterilizers should be equipped with B-process, N process. Proof of declaration of conformity.</p> <p>Amendment Request:</p> <p>Types of Cycles Process: Table Top Sterilizers</p>	Tender terms & conditions prevail.

	<p>should be equipped with <b>B-process</b> as per latest International standards. Proof of declaration of conformity.</p> <p>We would like to mention that N- Process does not guarantee 100% air removal and there can be some air pockets due to which steam may not be able to penetrate for complete sterilization of equipment, whereas B- process ensures 100% air removal using pre and post vacuum process which ensures effective and 100% sterilization.</p> <p>So the requested amendment may please be accepted and for quality procurement.</p>	
43.	<p>Item No. 3</p> <p>Chamber: Should be made of S.S.316. Chamber should have working pressure 2.2 bar &amp; design pressure up to 3.8 bar. Chamber should be equipped with electrically heated jacket for preheating on standby mode.</p> <p>Amendment Request:</p> <p>Chamber: Should be made of <b>S.S.316 / S.S 304</b>. Chamber should have working pressure 2.2 bar &amp; design pressure up to 3.8 bar. Chamber should be equipped with electrically heated jacket for preheating on standby mode.</p>	Tender terms & conditions prevail.
44.	<p>Item No. 3</p> <p>Door Design: Should have radially opening door with at least one or two locking bolts for enhanced door safety. The doors should come with silicon elastomeric rubber gasket to withstand temperature up to 140°C &amp; 20-30 psi.</p> <p>Amendment Request:</p> <p>Door Design: Should have <b>radially/ manually</b> opening door with at least one or two locking bolts for enhanced door safety. The doors should come with silicon elastomeric rubber gasket to withstand temperature up to 140°C &amp; 20-30 psi.</p>	Tender terms & conditions prevail.
45.	<p>Item No. 4</p> <p><b>DOUBLE DOOR WASHER DISINFECTOR 280-350 Litre(12-15 DIN Trays) WITH ACCESSORIES</b></p>	Tender terms & conditions prevail.



	<p>Amendment Request:</p> <p><b>DOUBLE DOOR WASHER DISINFECTOR 260 Liters or more (with minimum 12 DIN Trays) WITH ACCESSORIES</b></p>	
46.	<p>Item No. 4</p> <p>Chamber Capacity: Chamber capacity: Operational Volume should be able to process minimum 12 DIN trays (Approx480X250X50) to 15 Trays with 6 levels in single process. Should supply 12-15 Nos of standard Stainless Steel DIN trays. The chamber should be made of S.S. 316L quality with electro polished washed surfaces. The chamber edges should not have the pockets &amp; folds so as to avoid bacterial growth. The wash chamber should also be fitted with bright light for clear visibility of the washing process.</p> <p>Amendment Request:</p> <p>Chamber Capacity: Chamber capacity: Operational Volume should be able to process <b>minimum 12 DIN trays</b> (Approx480X250X50) in single process. Should supply <b>12 Nos</b> of standard Stainless Steel DIN trays. The chamber should be made of S.S. 316L quality with electro polished washed surfaces. The chamber edges should not have the pockets &amp; folds so as to avoid bacterial growth. The wash chamber should also be fitted with bright light for clear visibility of the washing process.</p> <p>As in the tender specification at point no. “d.” you have asked for a 6 level whereas at point 5 you have mentioned 4 level rack. So it is requested to please remove the level and ask only for the DIN capacity.</p>	<p>Tender terms &amp; conditions prevail.</p>
47.	<p>Item No. 4</p> <p>8. The device should be a medical device according to Directive 93/42 EEC concerning medical devices. Should be BIS/US FDA/European CE certified.</p>	<p>Tender terms &amp; conditions prevail.</p>

	<p>Amendment Request:</p> <p>8. The device should be a medical device according to Directive 93/42 EEC concerning medical devices. Should be BIS/US FDA/<b>European CE from 4 digit notified body.</b></p>	
48.	<p>Item No. 5</p> <p><b>PLASMA STRILIZER (Double door)-120-150 L (Material SS-316/SS-316L)</b></p> <p>Should provide simple and fast sterilization of medical devices at low temperature using Hydrogen Peroxide sterilization gas/plasma technology without any need to have additional Dryer.</p> <p>Amendment Request:</p> <p>Should provide simple and fast sterilization of medical devices at low temperature using Hydrogen Peroxide sterilization <b>plasma technology</b> without any need to have additional Dryer.</p>	Tender terms & conditions prevail.
49.	<p>Item No. 5</p> <p>Usable Rectangular chamber having volume of minimum 120L-150 litres.</p> <p>Amendment Request:</p> <p>Usable Rectangular chamber having volume of <b>minimum 120 litres (±5%).</b></p> <p>We would like to highlight that different manufacturers are having Plasma sterilizer with a little tolerance in usable chamber volumes. Hence the same may please be allowed as requested.</p>	Tender terms & conditions prevail.
50.	<p>Item No. 5</p> <p>Should be environment friendly and have no toxic by-products or harmful residues and should approval of EPA to guarantee its non-harmful feature.</p> <p>Amendment Request:</p> <p>Should be environment friendly and have no toxic</p>	Tender terms & conditions prevail.

	<p>by-products or harmful residues and <b>this should been tested by the manufacturer as per the manufacturer country's environmental protection Law.</b></p> <p>Kindly allow the requested amendment for healthy competition and wider participation. And asking for EPA approval to submit will restrict the participation to one company only and also EPA is required for US based company whereas the other manufacturer in other countries get their instrument tested for environmental protection as per their country environmental law's.</p>	
51.	<p>Item No. 5</p> <p>Should quote same make consumables having EPA-US/ European CE/BIS as mentioned below :</p> <p>Amendment Request:</p> <p>Should quote <b>same make / compatible consumables</b> having EPA-US/ European CE/ BIS/ <b>ISO</b> as mentioned below :</p>	Tender terms & conditions prevail.
52.	<p>Item No. 5</p> <p>H2O2 Sterilant 59% - Cassette or Cup= for 100 load cycles,</p> <p>Amendment Request:</p> <p>H2O2 Sterilant 59% - <b>Cassette/ Bottle/ Cup=</b> for 100 load cycles,</p> <p>Different manufacturer have own standard of machines. Some uses cassette or cup and some of uses bottles. So the requested amendment may please be allowed for healthy participation.</p>	Tender terms & conditions prevail.
53.	<p>Item No. 6</p> <p><b>ULTRASONIC CLEANER (40 L)</b> Capacity should be 40 L</p> <p><b>Amendment Request:</b></p>	Tender terms & conditions prevail.

	<p>ULTRASONIC CLEANER (<b>45 ± 5 L</b>) Capacity should be <b>45 ± 5 L</b></p> <p>Please allow the requested chamber volume as the same may differ a little for different manufactured Models.</p>	
54.	<p>Item No. 7</p> <p><b>HEAT SEALING MACHINE</b></p> <p>It should be of the same manufacturer as sterilizer and washer disinfector.</p> <p>Amendment Request:</p> <p><b>May please be deleted</b></p> <p>Generally no steam sterilizer &amp; washer disinfector company manufacturers Sealing machine and they are taking on OEM basis from other manufacturers. So this point may be deleted and the sealing machine can be quoted of a reputed manufacturer of the specification asked. If the point not deleted will restrict the wider participation.</p>	Tender terms & conditions prevail.
55.	<p><b>Item No. 10</b></p> <p><b>DRYING CABINET</b></p> <p>Should be automatic in operation</p> <p>Inner chamber should be made up of stainless steel-316 and outer chamber should be of SS-316</p> <p>Amendment Request:</p> <p>2. Inner chamber should be made up of <b>stainless steel-316/304</b> and outer chamber should be of <b>epoxy painted</b></p>	Tender terms & conditions prevail.
56.	<p>Item No. 10</p> <p>Should have heaters of minimum 2 KW</p> <p>Amendment Request:</p> <p>3. Should have heaters of <b>minimum 1.5 KW or</b></p>	Tender terms & conditions prevail.

	<b>more</b>	
57.	<p>Item No. 10</p> <p>Approximate size-275 L</p> <p>Amendment Request:</p> <p>5. Approximate size-<b>200 L or more</b></p>	Tender terms & conditions prevail.
58.	<p><b>Item No. 17</b></p> <p><b>CONTROL &amp; PACKING TABLE WITH TWO SHELVES FOR CLEAN AREA</b></p> <p>The worktop should be made of a robust wood-based core material, surfaced with plastic laminate in a soft beige colour that reduces reflection of light from the surface. All edges should be smooth. The extended width of the worktop should be designed to facilitate thorough inspection of instrument trays and allow the use of large wrapping material.</p> <p>Amendment Request:</p> <p>The worktop should be made of a robust wood-based core material, surfaced with plastic laminate in a soft beige colour/ <b>stainless steel</b> that reduces reflection of light from the surface. All edges should be smooth. The extended width of the worktop should be designed to facilitate thorough inspection of instrument trays and allow the use of large wrapping material.</p>	Tender terms & conditions prevail.
59.	<p>Item No. 17</p> <p>Should have double workspace. One workplace table should have 700 mm wide worktop and other workplace should have 1400 mm worktop.</p> <p>Amendment Request:</p> <p>6. Should have double workspace. One workplace table should have 700 mm wide worktop and <b>total</b> workplace should have 1400 mm worktop.</p>	<p>Item No. 17</p> <p>Should have double workspace. One workplace table should have 700 mm wide worktop and <b>total</b> workplace should have 1400 mm worktop.</p>
60.	<p>Item No. 21</p> <p><b>21. CLOSED TRANSPORT TROLLEY FROM STERILE STORE TO OT</b></p> <p>Trolley should be fitted with large stainless-steel</p>	Tender terms & conditions prevail.

	wheels (Ø 160 mm) for easier manoeuvrability  Amendment Request:  Trolley should be fitted with <b>study padded wheel for easier manoeuvrability and smooth noiseless movement.</b>	
61.	Item No. 29  <b>STORAGE CUPBOARD</b>  Dimension should be as per design.  Amendment Request:  <b>Please provide the dimension</b>	Tender terms & conditions prevail.
62.	Item No. 31  <b>CHANGE LOCKER -4 COMPARTMENTS</b>  Size of each compartment should be as per design  Amendment Request:  <b>Please provide the dimension</b>	Tender terms & conditions prevail
63.	Item No. 33  <b>OPEN STORAGE RACK</b>  Dimensions as per design.  Amendment Request:  <b>Please provide the dimension</b>	Tender terms & conditions prevail.
64.	Item No. 34  <b>OFFICE TABLE</b>  Size should be as per design.  Amendment Request:  <b>Please provide the dimension</b>	Tender terms & conditions prevail.
65.	<b>Furniture Items for CSSD</b>  <b>± 5% tolerance may please be allowed in sizes for furniture items</b>	Tender terms & conditions prevail

	A minimum tolerance of 5% may please be allowed.	
66.	<p>NIT Vol. IV at Page no. 19</p> <p>Institute will provide one point water&amp; drain supply and further distribution will be responsibility of bidder as per approved layout.</p> <p>Institute will provide one point water&amp; drain supply <b>at designated point mentioned in the layout by the bidder</b> and further distribution will be responsibility of bidder as per approved layout.</p>	Tender terms & conditions prevail.
67.	<p><b>NIT Vol. V (BOQ) Item no. 37</b></p> <p>RO with DM Plant 2000 LPM as per technical specification</p> <p><b>RO of 2000 LPH with TDS less than 10 ppm. (output water)</b></p> <p>These plant should be liter per hour instead of Liter per minute (LPM). Further the DM plant may please also be removed.</p>	RO of 2000 LPH with TDS less than 10 ppm (Output water)
68.	<p>NIT Vol. 01 at Page no. 05</p> <p>2.2 The Applicant should meet the following minimum criteria for Pre-Qualification:</p> <p><b>Added Point (V)</b> The bidder must have experience of supplying the steam sterilizer of the same manufacturer quoted in the tender</p> <p>As you know that the steam sterilizer is the heart of CSSD department so the bidder should have the past experience of supplying &amp; maintaining the steam sterilizer quoted in the tender. So you must asked for the experience of the bidder in supplying the steam sterilizer of the same make.</p>	Tender terms & conditions prevail.
69.	<p>NIT Vol.-I at Page 5</p> <p>COMPLETION PERIOD: 4 months from the date of order of commencement.</p>	Tender terms & conditions prevail.

	COMPLETION PERIOD: <b>6 months</b> from the date of order of commencement.	
70.	<p>NIT Vol. IV at Page no. 22</p> <p>Manufacturer's Authorization</p> <p>Manufacturer Authorization: Eligible bidders quoting as an Indian Agent should submit a Manufacturer's Authorization letter as per format enclosed at Annexure-E of Vol-III from the Foreign Principal / Manufacturer, with name of manufacturing company for major products quoted by them as per given format as detailed below:</p> <p>A. Exclusive Items</p> <ol style="list-style-type: none"> <li>1 Horizontal Double Sliding door autoclave</li> <li>2 High Speed Sterilizer 250 L</li> <li>3 Rapid Sterilizer (Flash Autoclave)</li> <li>4 Double Door Washer Disinfecter</li> <li>5 Plasma/H2O2/Low Temperature Sterilizer</li> </ol> <p>B. Non-Exclusive Like:</p> <ol style="list-style-type: none"> <li>1. Ultrasonic Cleaner</li> <li>2. Heat Sealing Machine</li> <li>3. Drying Cabinet</li> </ol> <p>For other small items Manufacturer authorization should not be required.</p> <p>It is requested that the Manufacturing authorization for equipment may please be asked as requested.</p>	Tender terms & conditions prevail.
71.	<p><b>CSSD Area</b></p> <p>Please specify the area for CSSD and also the drawing with dimension preferably CAD should be provided by the tendering authority.</p>	Bidders are requested to visit the site.
72.	<p><b>Warranty &amp; CAMC</b></p> <p>Please mention that the machine related consumables list are to be specified separately in the technical bid as the same will not be covered under the warranty &amp; CAMC.</p>	Tender terms & conditions prevail.
73.	<p><b>Technical Package I &amp; II</b></p> <p><b>You are requested to kindly ask in the technical package that the quoted model &amp;</b></p>	Tender terms & conditions prevail.



	<p><b>make and catalogue of major items along with manufacturer authorization must be submitted by the bidder i.e. for steam sterilizer, washer disinfectant, plasma sterilizer, rapid sterilizer. The Bidder has to submit technical compliance statement along with supporting documents. The above should be the part of the technical evaluation before opening of financial bid and deciding the L1 Bidder.</b></p> <p>Asking the complete technical details of the quoted system along with submission of catalogue &amp; manufacturer authorization are the general tender criteria followed by Govt. of India institutes including HSCC. Otherwise there can be chances of manipulation by any vendor / participants later-on on seeing the competition to get financial advantage. For such a huge procurement of value 4.6 Crore</p>	
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All other terms & conditions remain unchanged.

Chief General Manager  
HSCC (India) Ltd.