

All Bidders**Amendment –II**

Project: Supply, Installation, Testing & Commissioning of CSSD for Super Speciality Block at Indira Gandhi Medical College, Shimla, H.P.

IFB No. HSCC/SES/CSSD/SSB/Shimla/2019 dated 31.01.2019

This has reference to above IFB.

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

Sr. No.	Bidders' Queries	Reply
1	<p>1. Volume IV Page no 2 <u>Horizontal Steam Sterilizer 550-600L or more</u> & <u>High Speed Sterilizer- Double door 250L with accessories.</u> (Control System)</p> <p>As per Specification Control system should have touch sensitive, 7 inches or more color display interface at operator loading side while it should have normal interface at unloading side.</p> <p>It is requested that <u>Control system should have touch sensitive ,5 inches or more color display interface at operator loading side while it should have normal interface at unloading side</u></p> <p>We request to give bigger range so that most of the manufacture can also quote. <u>Kindly do the same changes for both the sterilizers.(550-600L and 250L)</u></p>	<p><u>Horizontal Steam Sterilizer</u> <u>Double door 550-600L or more</u> & <u>High Speed Sterilizer-</u> <u>Double door 250L with accessories.</u></p> <p>Control system should have touch sensitive ,5-7 inches or more color display interface at operator loading side while it should have normal interface at unloading side.</p>
2	<p>2. Vol IV Page no 7 Item No: 4Point No:d</p> <p><u>As per Specification</u> Chamber Capacity: Operational volume should be 300 to 350L. Should supply 12 Nos of standard stainless steel DIN trays. It should be able to process minimum 12 DIN trays (Approx 480x250x50) in single process. The chamber should be made of SS304 or SS 316L quality with electro polished washed surfaces.</p>	<p>Chamber Capacity: Operational volume should be able to process minimum 12 DIN trays (Approx 480x250x50) in single process. The chamber should be made of SS 316L quality with electro polished washed surfaces.</p>

	<p><u>Request</u> Chamber Capacity: Operational volume should be 250 to 350L. Should supply 12 Nos of standard stainless steel DIN trays. It should be able to process minimum 12 DIN trays (Approx 480x250x50) in single process. The chamber should be made of SS 316L quality with electro polished washed surfaces.</p> <p>Since the capacity of the wash chamber is always measured in DIN Trays according to EN standards and Litre capacity is always be differ from one to other, while measuring the actual capacity of the wash chamber it is only depend on to accommodate the number of DIN trays in the chamber . So Litre capacity should be deleted and only DIN capacity should be mentioned.</p>	
3.	<p>3. Vol IV Page no 8 Point no 5 <u>As per Specification</u> The washer disinfector shall be supplied with universal rack, 4 level racks for instrument tray, full size instrument tray as well as stop valves, anti-suction device and plastic water trap . Requested</p> <p>The washer disinfector shall be supplied with universal rack, 6 level racks for instrument tray, full size instrument tray as well as stop valves, anti-suction device and plastic water trap.</p> <p>Since you have asked for 12 DIN Trays capacity and which is practically possible to use in a 6 level racks. So we request you to kindly change it from 4 Level Racks to 6 Level racks.</p>	4 -6 Levels racks
4.	<p>4. Vol IV Page no 8 Item no 5 Point no 4 <u>Plasma/H2O2/Low Temperature Sterilizer(Double Door)- 120-150L</u> As per specification</p> <p>i)The sterilizer process must have maximum material device manufacturer's recommendations from major endoscopic equipment manufacturers.</p> <p>Point should be deleted</p> <p>Since it is only available with one company and being an open tender it should be generalized so that most of the bidders can participate.</p> <p>ii) Point no 4</p>	<p>i) Deleted</p> <p>ii) 100 – 120 L prevail.</p> <p>iii) Should be environment friendly and have no toxic by products or harmful residue and should approval of EPA or equivalent to guarantee its non-harmful feature by bidder.</p> <p>iv) Consumables having EPA-US/CE deleted</p>

	<p><u>As per specification</u></p> <p>Usable rectangular chamber having volume of minimum 120-150 Liters</p> <p><u>Request</u></p> <p>Usable rectangular chamber having volume of minimum 100-120 Liters or 90-120L</p> <p>Since most of the leading manufacturers are having usable chamber volume is around 100L, so it should have given wide range for a bigger participation.</p> <p>iii) Point no 8</p> <p><u>As per specification</u></p> <p>Should be environment friendly and have no toxic byproducts or harmful residue and should approval of EPA to guarantee its non-harmful feature.</p> <p><u>Request</u></p> <p>Should be environment friendly and have no toxic byproducts or harmful residue.</p> <p>Please note EPA is an American agency which normally gives certifications for environment protection of systems which are manufactured in US only. Since our systems are based on EN standards which do not required EPA, so should be deleted.</p> <p>iv) Point no 14</p> <p><u>As per specification</u></p> <p>Should quote same make consumables having EPA - US/CE as mentioned below:</p> <ul style="list-style-type: none"> a) H₂O₂ Sterilant 59%- Cassette or cup=100 load cycles b) Chemical Indicator strips-2000 strips for approx 100 Load Cycle c) Biological Indicator vials =100 nos <p><u>Request</u></p> <p>Should quote consumables having EPA-US/CE as mentioned below:</p> <ul style="list-style-type: none"> a) H₂O₂ Sterilant 59%- Cassette or cup=100 load cycles b) Chemical Indicator strips-2000 strips for approx 100 Load Cycle c) Biological Indicator vials =100 nos <p>Please note the monitoring consumables are third party items and all plasma sterilizer manufacturers do produce or manufacture these items, so should be removed or amended.</p>	
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5.	<p><u>Drying Cabinet</u></p> <p>Vol IVPage No. 9 Item no 8 , Point No 6 <u>As per technical specification</u></p> <p>Should be the same manufacturer of the sterilizer and washer disinfector.</p> <p><u>Request</u></p> <p>Should be deleted.</p> <p><u>Since this point is restricting the competition as some of the leading brand is only having either Sterilizer or Washer disinfector in their range of products. So this point should be deleted to have a healthy competition.</u></p>	Should be the same manufacturer of the sterilizer and washer disinfector – Deleted.
6.	<p>Item No. 1: Horizontal Sterilizer 550L – 600L or More</p> <p>Page No. 1 of Technical Specification: 1. Chamber & Doors: The chamber and doors should be made of solid, high quality 316L Stainless steel. The chamber should be jacketed to ensure the temperature uniformity in chamber. The chamber floor is slightly sloped towards an internal drain to facilitate drainage.</p> <p><u>Request</u></p> <p>Chamber thickness should be specified as minimum 8 mm for better against high thermo - mechanical stress due to high temperature & high pressure</p>	Tender terms & conditions prevail.
7.	<p>Page No. 1 of Technical Specification: 2. Surface Treatment The resultant surface should be polished to less than 0.8 µm fineness to protect against corrosion.</p> <p>Page No. 1 of Technical Specification: 2. Surface Treatment <u>Request</u></p> <p>The resultant surface should be polished to less than 0.2 µm fineness to protect against corrosion. Kindly amend the same.</p>	The resultant surface should be polished to less than 0.2 µm fineness to protect against corrosion.
8	<p>Page No. 1 of Technical Specification: 3. Insulation: The sterilizer jacket and door should be completely insulated to keep the autoclave cool on the outside. The insulation should be completely encased in rigid removable sheet housing. <u>Request</u> Page No. 1 of Technical Specification: 3. Insulation:</p>	The Insulation Material Should Be Non - Toxic, Low Thermal Conductivity, Fire Resistant & Should Not Release Any Particles.

	<p>The sterilizer jacket and door should be completely insulated to keep the autoclave cool on the outside. The Insulation Material Should Be Non - Toxic, Low Thermal Conductivity, Fire Resistant & Should Not Release Any Particles. Kindly amend the same.</p>	
	<p>Page No. 2 of Technical Specification: c) Pipes, Valves and Components: The piping system should be made of Stainless Steel / Brass / Copper.</p> <p><u>Request</u></p> <p>Page No. 2 of Technical Specification: c) Pipes, Valves and Components: The piping system should be made of Stainless Steel 316L. Kindly amend the same.</p>	Tender terms & conditions prevail.
10	<p>Page No. 2 of Technical Specification: c) Pipes, Valves and Components All the process valves should be stainless steel or Copper Valves or Red Brass Valves & should be pneumatically/electrically operated piston valves for longer trouble free operations.</p> <p><u>Request</u></p> <p>Page No. 2 of Technical Specification: c) Pipes, Valves and Components All the process valves should be stainless steel 316L. Kindly amend the same.</p>	Tender terms & conditions prevail.
11	<p>Page No. 2 of Technical Specification: Primary piping & fittings should be stainless steel threaded or stainless steel triclamp fittings.</p> <p><u>Request</u></p> <p>Page No. 2 of Technical Specification: Primary piping & fittings should be stainless steel threaded and stainless steel triclamp fittings for wherever necessary for easy maintenance & hermitically sealing. Kindly amend the same.</p>	Tender terms & conditions prevail.
	<p>Page No. 2 of Technical Specification: Primary components: 316 quality triclamps or threaded fitting components like – Manual valve, non- return valve, pressure regulator, pneumatic valves, and steam trap etc.</p> <p><u>Request</u></p> <p>Page No. 2 of Technical Specification: Primary piping & fittings should be stainless steel threaded and stainless steel triclamp fittings for wherever necessary for easy maintenance & hermitically sealing. Kindly add above point.</p>	Tender terms & conditions prevail.
12	<p>Page No. 2 of Technical Specification: 3. Electrical Components: the terminals & contacts</p>	Tender terms & conditions prevail.

	<p>should be housed in a water tight cabinet while the other electrical component should be directly mounted on sterilizer.</p> <p><u>Request</u></p> <p>Page No. 2 of Technical Specification: All Electrical & Electronic components including the terminals & contacts should be housed in a IP 55 protected water tight Electrical cabinet and should be directly mounted on sterilizer. No Electrical panels/connections should be seen outside the Steam Sterilizer and all the service should be done from the frontal service only. The Sterilizer should have side panels made of SS AISI 304 grade. Kindly amend the same.</p>	
13	<p>Page No. 2 of Technical Specification: e) Control System The control system should be microprocessor based PLC system specially designed for sterilization application.</p> <p><u>Request</u></p> <p>Page No. 2 of Technical Specification: e) Control System The control system should be microprocessor based Dual PLC system specially designed for sterilization application.</p> <p>Dual PLC is better as per EN 285 Standards. Kindly amend the same.</p>	Tender terms & conditions prevail.
14	<p>Page No. 2 of Technical Specification: Apart from main PLC based control system the sterilizer should also have additional independent monitoring & documentation system which constantly cross checks the safety systems & time.</p> <p><u>Request</u></p> <p>Page No. 2 of Technical Specification: Dual PLC is better as per EN 285 Standards. Kindly amend the same.</p>	Tender terms & conditions prevail.
15	<p>Page No. 2 of Technical Specification: These access levels should be user selectable. The control system should have CPU processor with battery back-up & nonvolatile memories, Digital input/output controls, analog measuring inputs & COM ports for printer & PC connectivity.</p> <p><u>Request</u></p> <p>Page No. 2 of Technical Specification: These access levels should be user selectable. The control system should have CPU processor with battery back-up & nonvolatile memories, Digital input/output controls, analog measuring inputs & COM ports for printer & PC connectivity alongwith RS 232 & RJ 45 as per current standards.</p>	These access levels should be user selectable. The control system should have CPU processor with battery back-up & nonvolatile memories, Digital input/output controls, analog measuring inputs & COM ports for printer & PC connectivity along with RS 232 & RJ 45 as per current standards.

	Kindly amend the same.	
16	<p>Page No. 2 of Technical Specification: f) Temperature and Pressure Sensors: 1. The sterilizer should have at least 2 temperature & pressure sensors one at chamber drain & one in Jacket. It should also have temperature & pressure sensor in chamber.</p> <p><u>Request</u></p> <p>Page No. 2 of Technical Specification: f) Temperature and Pressure Sensors: The sterilizer should have at least 2 temperature sensor & 2 pressure transducers for chamber drain and one Pressure Transducer & One temperature sensor in Jacket(as per EN 285 standards). Kindly amend the same.</p>	<p>f) Temperature and Pressure Sensors: The sterilizer should have at least 2 temperature sensor & 2 pressure transducers for chamber drain and one Pressure Transducer& One temperature sensor in Jacket(as per EN 285 standards).</p>
17	<p>Page No. 2 of Technical Specification: f) Temperature and Pressure Sensors: 2. The sensors should be PT100 sensors to confirm Class A of the IEC 571 standard, with accuracy of $\pm 0.1^{\circ}\text{C}$ while the pressure sensor should have the accuracy 1% over the range of 0-5 bar.</p> <p><u>Request</u></p> <p>Page No. 2 of Technical Specification: f) Temperature and Pressure Sensors: 2. The sensors should be PT100 sensors to confirm Class A of the IEC 751 standard, with accuracy of $\pm 0.1^{\circ}\text{C}$ while the pressure sensor should have the accuracy 1% over the range of 0-5 bar. Kindly amend the same.</p>	<p>f) Temperature and Pressure Sensors: 2. The sensors should be PT100 sensors to confirm Class A of the IEC 751 standard, with accuracy of $\pm 0.1^{\circ}\text{C}$ while the pressure sensor should have the accuracy 1% over the range of 0-5 bar.</p>
18	<p>Page No. 2 of Technical Specification: g) Alarm All the alarms should be audio and visual.</p> <p><u>Request</u></p> <p>Page No. 2 of Technical Specification: g) Alarm All the alarms should be audio, visual and printed. Kindly amend the same.</p>	<p>Tender terms & conditions prevail.</p>
19	<p>Page No. 2 of Technical Specification: h) Loading/Unloading system: Sterilizer should have the two rails for easy loading, shelf rack with shelves (carriage) with 1 set of loading and unloading trolley.</p> <p><u>Request</u></p> <p>Page No. 2 of Technical Specification: h) Loading/Unloading system: The sterilizer should be supplied with two External Trolley & one Internal Trolley and the applicable number of STU baskets and should not have guide rails inside the chamber as this will have many folds, joints & sharp</p>	<p>h)Loading/Unloading system: The sterilizer should be supplied with two External Trolley & one Internal Trolley and the applicable number of STU baskets and should not have guide rails inside the chamber as this will have many folds, joints & sharp edges thus leading to personal injury while cleaning and inefficient cleaning leading to contamination.</p>

	edges thus leading to personal injury while cleaning and inefficient cleaning leading to contamination. Kindly amend the same.	
20	<p>Page No. 2 of Technical Specification: i) Cycle Documentation – Printer: The autoclave should be equipped with an alpha-numeric Laser/thermal printer which prints the each cycle parameter performed by the sterilizer.</p> <p><u>Request</u></p> <p>Page No. 2 of Technical Specification: i) Cycle Documentation – Printer: The autoclave should be equipped with an ink type printer which prints the each cycle parameter performed by the sterilizer.</p> <p>Ink type printer is good for Long Storage Records of Cycle Printout. We request you to kindly amend the same.</p>	The autoclave should be equipped with an alpha-numeric Laser/thermal printer/ink printer which prints the each cycle parameter performed by the sterilizer.
21	<p>Page No. 3 of Technical Specification: j) Specify water consumption levels.</p> <p><u>Request</u></p> <p>Page No. 3 of Technical Specification: j) Specify water consumption levels. It should have 95% Water saving system and should not require any cooling or chilled water for vacuum pump performance and it should need water (treated softened/RO) only for built in steam generator. To Specify water consumption levels: a. Water for Vacuum Pump: b. Water(treated softened/RO) for Built in Steam Generator: Kindly amend the same.</p>	Tender terms & conditions prevail.
22	<p>Page No. 3 of Technical Specification: (k) Vacuum Pump High vacuum pump (water ring type) with recycling facility for removal of air within the chamber should be provided & mounted on vibration isolator for quite operations.</p> <p><u>Request</u></p> <p>Page No. 3 of Technical Specification: (k) Vacuum Pump High performance vacuum pump should be provided & mounted on vibration isolator for quite operations. Kindly amend the above point.</p>	Tender terms & conditions prevail.
23	<p>Page No. 3 of Technical Specification: (n) Directives & Standards: It should meet EN ISO / IEC directives and product should be US FDA/European CE certified with four digit notified body number.</p> <p><u>Request</u></p>	Tender terms & conditions prevail.

	<p>Page No. 3 of Technical Specification: (n) Directives & Standards: The Sterilizer should comply with the Medical Devices Directive 93/42 / EEC , according 2007/47 / EC, and should be validated in compliance with the UNI EN ISO 17665-1 : 2007 relative to the steam sterilization. The Sterilizer should follow the EN 285 : 2009 standard. The Sterilizers also should comply with the directives 2004/108 / EC (EMC) and 2006/ 95 / EC (LVD) and electrical codes IEC 61010-1 : 2013 , IEC 61010-2040 : 2005 , IEC 60204-1 : 2010, EN 61326-1:2013 . The pressure vessels should be in compliance with PED 2014/68/UE(latest edition). It should be European CE/ US FDA certified by notified body with four digit identification number. Kindly amend the same.</p>	
24	<p>Page No. 3 of Technical Specification: (n) Directives & Standards: The manufacturer should have ISO 13485:2003 and EN 285 for Large Autoclaves (Europe) or USA: ST8 – Hospital Sterilizers</p> <p><u>Request</u></p> <p>Page No. 3 of Technical Specification: (n) Directives & Standards: The manufacturer should have ISO 13485:2012 and ISO 9001 : 2015 Quality systems. Kindly amend the same.</p>	Tender terms & conditions prevail.
25	<p>Page No. 3 of Technical Specification (p) Steam Sterilizer should have provision for connecting a ¾” line terminating in the shutoff valve, non-return valve, pressure relief valve, steam riser, condensate drain and other essential accessories (for future steam connection from the central boiler).</p> <p><u>Request</u></p> <p>Page No. 3 of Technical Specification (p) Steam Sterilizer should have provision for connecting a ¾” line terminating in the shutoff valve, non-return valve, pressure relief valve, steam riser, condensate drain and other essential accessories (for future steam connection from the central boiler) with in built steam filter. Kindly amend the same.</p>	Tender terms & conditions prevail.
	Item No. 2 – High Speed Sterilizer – Double Door 250 Litres with Accessories	
26	<p>Page No. 4 of Technical Specification: 1. Chamber & Doors: The chamber and doors should be made of solid, high quality 316L Stainless steel. The chamber should be jacketed to ensure the temperature uniformity in chamber. The chamber floor is slightly sloped towards an internal drain to facilitate</p>	Tender terms & conditions prevail.

	<p>drainage.</p> <p><u>Request</u></p> <p>Page No. 4 of Technical Specification:</p> <p>Chamber thickness should be specified as minimum 8 mm for better against high thermo - mechanical stress due to high temperature & high pressure</p> <p>Please add in the specification</p>	
	<p>Page No. 4 of Technical Specification:</p> <p>2. Surface Treatment</p> <p>The resultant surface should be polished to less than 0.8 µm fineness to protect against corrosion.</p> <p><u>Request</u></p> <p>Page No. 4 of Technical Specification:</p> <p>2. Surface Treatment</p> <p>The resultant surface should be polished to less than 0.2 µm fineness to protect against corrosion.</p> <p>Kindly amend the same.</p>	<p>The resultant surface should be polished to less than 0.2 µm fineness to protect against corrosion.</p>
27	<p>Page No. 4 of Technical Specification:</p> <p>3. Insulation:</p> <p>The sterilizer jacket and door should be completely insulated to keep the autoclave cool on the outside. The insulation should be completely encased in rigid removable sheet housing.</p> <p><u>Request</u></p> <p>Page No. 4 of Technical Specification:</p> <p>3. Insulation:</p> <p>The sterilizer jacket and door should be completely insulated to keep the autoclave cool on the outside. The Insulation Material Should Be Non - Toxic, Low Thermal Conductivity, Fire Resistant & Should Not Release Any Particles.</p> <p>Kindly amend the same.</p>	<p>The Insulation Material Should Be Non - Toxic, Low Thermal Conductivity, Fire Resistant & Should Not Release Any Particles.</p>
	<p>Page No. 4 of Technical Specification:</p> <p>c) Pipes, Valves and Components:</p> <p>The piping system should be made of Stainless Steel / Brass / Copper.</p> <p><u>Request</u></p> <p>Page No. 4 of Technical Specification:</p> <p>c) Pipes, Valves and Components:</p> <p>The piping system should be made of Stainless Steel 316L.</p> <p>Kindly amend the same.</p>	<p>Tender terms & conditions prevail.</p>
28	<p>Page No. 4 of Technical Specification:</p> <p>c) Pipes, Valves and Components</p> <p>All the process valves should be stainless steel or Copper Valves or Red Brass Valves & should be</p>	<p>Tender terms & conditions prevail.</p>

	<p>pneumatically/electrically operated piston valves for longer trouble free operations.</p> <p><u>Request</u></p> <p>Page No. 4 of Technical Specification: c) Pipes, Valves and Components All the process valves should be stainless steel 316L. Kindly amend the same.</p>	
29	<p>Page No. 4 of Technical Specification: 1. Primary piping & fittings should be stainless steel threaded or stainless steel triclamp fittings</p> <p><u>Request</u></p> <p>Page No. 4 of Technical Specification: Primary piping & fittings should be stainless steel threaded and stainless steel triclamp fittings for wherever necessary for easy maintenance & hermitically sealing. Kindly amend the same.</p>	Tender terms & conditions prevail.
30	<p>Page No. 4 of Technical Specification: Primary components: 316 quality triclamps or threaded fitting components like – Manual valve, non- return valve, pressure regulator, pneumatic valves, and steam trap etc.</p> <p><u>Request</u></p> <p>Page No. 4 of Technical Specification: Primary piping & fittings should be stainless steel threaded and stainless steel triclamp fittings for wherever necessary for easy maintenance & hermitically sealing. Kindly add above point.</p>	Tender terms & conditions prevail.
31	<p>Page No. 4 of Technical Specification: Electrical Components: the terminals & contacts should be housed in a water tight cabinet while the other electrical component should be directly mounted on sterilizer.</p> <p><u>Request</u></p> <p>Page No. 4 of Technical Specification: All Electrical & Electronic components including the terminals & contacts should be housed in a IP 55 protected water tight Electrical cabinet and should be directly mounted on sterilizer. No Electrical panels/connections should be seen outside the Steam Sterilizer and all the service should be done from the frontal service only. The Sterilizer should have side panels made of SS AISI 304 grade. Kindly amend the same.</p>	Tender terms & conditions prevail.

32	<p>Page No. 4 of Technical Specification: e) Control System The control system should be microprocessor based PLC system specially designed for sterilization application.</p> <p><u>Request</u></p> <p>Page No. 4 of Technical Specification: e) Control System The control system should be microprocessor based Dual PLC system specially designed for sterilization application.</p> <p>Dual PLC is better as per EN 285 Standards. Kindly amend the same.</p>	Tender terms & conditions prevail.
33	<p>Page No. 5 of Technical Specification: Apart from main PLC based control system the sterilizer should also have additional independent monitoring & documentation system which constantly cross checks the safety systems & time.</p> <p><u>Request</u></p> <p>Page No. 5 of Technical Specification:</p> <p>Dual PLC is better as per EN 285 Standards. Kindly amend the same.</p>	Tender terms & conditions prevail.
34	<p>Page No. 5 of Technical Specification: These access levels should be user selectable. The control system should have CPU processor with battery back-up & nonvolatile memories, Digital input/output controls, analog measuring inputs & COM ports for printer & PC connectivity.</p> <p><u>Request</u></p> <p>Page No. 5 of Technical Specification: These access levels should be user selectable. The control system should have CPU processor with battery back-up & non volatile memories, Digital input/output controls, analog measuring inputs & COM ports for printer & PC connectivity alongwith RS 232 & RJ 45 as per current standards. Kindly amend the same.</p>	These access levels should be user selectable. The control system should have CPU processor with battery back-up & nonvolatile memories, Digital input/output controls, analog measuring inputs & COM ports for printer & PC connectivity alongwith RS 232 & RJ 45 as per current standards.
35	<p>Page No. 5 of Technical Specification: f) Temperature and Pressure Sensors: 1. The sterilizer should have at least 2 temperature & pressure sensors one at chamber drain & one in Jacket. It should also have temperature & pressure sensor in chamber.</p> <p><u>Request</u></p> <p>Page No. 5 of Technical Specification: f) Temperature and Pressure Sensors: The sterilizer should have at least 2 temperature sensor & 2 pressure transducers for chamber drain and one</p>	<p>f) Temperature and Pressure Sensors: The sterilizer should have at least 2 temperature sensor & 2 pressure transducers for chamber drain and one Pressure Transducer & One temperature sensor in Jacket(as per EN 285 standards).</p>

	Pressure Transducer & One temperature sensor in Jacket (as per EN 285 standards). Kindly amend the same.	
36	<p>Page No. 5 of Technical Specification: f) Temperature and Pressure Sensors: 2. The sensors should be PT100 sensors to confirm Class A of the IEC 571 standard, with accuracy of $\pm 0.1^{\circ}\text{C}$ while the pressure sensor should have the accuracy 1% over the range of 0-5 bar.</p> <p><u>Request</u></p> <p>Page No. 5 of Technical Specification: f) Temperature and Pressure Sensors: 2. The sensors should be PT100 sensors to confirm Class A of the IEC 751 standard, with accuracy of $\pm 0.1^{\circ}\text{C}$ while the pressure sensor should have the accuracy 1% over the range of 0-5 bar. Kindly amend the same.</p>	<p>f) Temperature and Pressure Sensors: 2. The sensors should be PT100 sensors to confirm Class A of the IEC 751 standard, with accuracy of $\pm 0.1^{\circ}\text{C}$ while the pressure sensor should have the accuracy 1% over the range of 0-5 bar.</p>
37	<p>Page No. 5 of Technical Specification: g) Alarm All the alarms should be audio and visual.</p> <p><u>Request</u></p> <p>Page No. 5 of Technical Specification: g) Alarm All the alarms should be audio, visual and printed. Kindly amend the same.</p>	Tender terms & conditions prevail.
38	<p>Page No. 5 of Technical Specification: h) Loading/Unloading system: Sterilizer should have the two rails for easy loading, shelf rack with shelves (carriage) with 1 set of loading and unloading trolley.</p> <p><u>Request</u></p> <p>Page No. 5 of Technical Specification: h) Loading/Unloading system: The sterilizer should be supplied with two External Trolley & one Internal Trolley and the applicable number of STU baskets and should not have guide rails inside the chamber as this will have many folds, joints & sharp edges thus leading to personal injury while cleaning and inefficient cleaning leading to contamination Kindly amend the same.</p>	<p>h) Loading/Unloading system: The sterilizer should be supplied with two External Trolley & one Internal Trolley and the applicable number of STU baskets and should not have guide rails inside the chamber as this will have many folds, joints & sharp edges thus leading to personal injury while cleaning and inefficient cleaning leading to contamination</p>
39	<p>Page No. 5 of Technical Specification: i) Cycle Documentation – Printer: The autoclave should be equipped with an alpha-numeric Laser/thermal printer which prints the each cycle parameter performed by the sterilizer.</p> <p><u>Request</u></p> <p>Page No. 5 of Technical Specification: i) Cycle Documentation – Printer:</p>	The autoclave should be equipped with an alpha-numeric Laser/thermal printer/ink type printer which prints the each cycle parameter performed by the sterilizer.

	<p>The autoclave should be equipped with an ink type printer which prints the each cycle parameter performed by the sterilizer.</p> <p>Ink type printer is good for Long Storage Records of Cycle Printout. We request you to kindly amend the same.</p>	
40	<p>Page No. 5 of Technical Specification: j) Specify water consumption levels.</p> <p><u>Request</u></p> <p>Page No. 5 of Technical Specification: j) Specify water consumption levels. It should have 95% Water saving system and should not require any cooling or chilled water for vacuum pump performance and it should need water (treated softened/RO) only for built in steam generator. To Specify water consumption levels: a. Water for Vacuum Pump: b. Water(treated softened/RO) for Built in Steam Generator: Kindly amend the same.</p>	Tender terms & conditions prevail.
41	<p>Page No. 5 of Technical Specification: (k) Vacuum Pump High vacuum pump (water ring type) with recycling facility for removal of air within the chamber should be provided & mounted on vibration isolator for quite operations.</p> <p><u>Request</u></p> <p>Page No. 5 of Technical Specification: (k) Vacuum Pump High performance vacuum pump should be provided & mounted on vibration isolator for quite operations. Kindly amend the above point.</p>	Tender terms & conditions prevail.
42	<p>Page No. 6 of Technical Specification: (n) Directives & Standards: It should meet EN ISO / IEC directives and product should be US FDA/European CE certified with four digit notified body number.</p> <p><u>Request</u></p> <p>Page No. 6 of Technical Specification: (n) Directives & Standards: The Sterilizer should comply with the Medical Devices Directive 93/42 / EEC , according 2007/47 / EC, and should be validated in compliance with the UNI EN ISO 17665-1 : 2007 relative to the steam sterilization. The Sterilizer should follow the EN 285 : 2009 standard. The Sterilizers also should comply with the directives 2004/108 / EC (EMC) and 2006/ 95 / EC (LVD) and electrical codes IEC 61010-1 : 2013 , IEC 61010-2040 : 2005 , IEC 60204-1 : 2010, EN 61326-1:2013 . The pressure vessels should be in compliance with PED 2014/68/UE(latest edition). It should be European CE/ US FDA certified by notified body with four digit identification number</p>	Tender terms & conditions prevail.

43	<p>Page No. 6 of Technical Specification: (n) Directives & Standards: The manufacturer should have ISO 13485:2003 and EN 285 for Large Autoclaves (Europe) or USA: ST8 – Hospital Sterilizers</p> <p><u>Request</u></p> <p>Page No. 6 of Technical Specification: (n) Directives & Standards: The manufacturer should have ISO 13485:2012 and ISO 9001 : 2015 Quality systems.</p>	Tender terms & conditions prevail.
44	<p>Item No. 3 - RAPID STERILIZER (FLASH AUTOCLAVE)TABLE TOP STERILIZER WITH ACCESSORIES FOR TSSU</p>	
	<p>Page No. 6 of Technical Specification: Capacity: minimum 20 L</p> <p><u>Request</u></p> <p>Page No. 6 of Technical Specification: 2. Capacity: minimum 18-20 L</p>	Capacity: minimum 18-20 L
	<p>Page No. 7 of Technical Specification: Item No. 4 - DOUBLE DOOR WASHER DISINFECTOR 300-350 Litre WITH ACCESSORIES</p> <p><u>Request</u></p> <p>Page No. 7 of Technical Specification: Should be specified in useable chamber capacity in terms of 12 DIN Trays Processing Capacity. It should be noted that every OEM has different design and chamber capacity.</p>	Tender terms & conditions prevail.
	<p>Page No. 7 of Technical Specification: d. Chamber Capacity: Chamber capacityoperational Volume should be 300 to 350 L. Should supply 12 Nos of standard Stainless Steel DIN trays. It should also be able to process minimum 12 DIN trays (Approx480X250X50) in single process. The chamber should be made of S.S. 304 or S.S. 316L quality with electro polished washed surfaces. The chamber edges should not have the pockets & folds so as to avoid bacterial growth. The wash chamber should also be fitted with bright light for clear visibility of the washing process. Chamber dimension should suit the capacity.</p> <p><u>Request</u></p> <p>Page No. 7 of Technical Specification: d. Should be specified in useable chamber capacity in terms of 12 DIN trays processing capacity and chamber material should be SS AISI 316L for better against chemo thermal stress & corrosion and for better cleaning</p> <p>Kindly amend the same.</p>	Chamber Capacity: Operational volume should be able to process minimum 12 DIN trays (Approx 480x250x50) in single process. The chamber should be made of SS 316L quality with electro polished washed surfaces.
	<p>Page No. 7 of Technical Specification: Washer should have following features:</p>	Tender terms & conditions prevail.

	<p>For shortest possible filling and draining phases, higher capacity quick opening valves should be used so that short total process time is achieved. The design should focus on saving the environment through reduced consumptions of all utilities.</p> <p><u>Request</u></p> <p>Page No. 7 of Technical Specification: Washer should have following features: a) For shortest possible filling and draining phases, higher capacity pneumatic valves should be used so that short total process time is achieved. The design should focus on saving the environment through reduced consumptions of all utilities.</p> <p>Kindly amend as pneumatic valves are better for long run & high durability.</p>	
	<p>Page No. 7 of Technical Specification: g. Data interface RS232 should be available.</p> <p><u>Request</u></p> <p>Page No. 7 of Technical Specification: Data interface RS 232 & RJ45 LAN should be available. Kindly amend as RS232 & RJ45 LAN is better.</p>	<p>Data interface RS 232 & RJ45 LAN should be available.</p>
	<p>Page No. 7 of Technical Specification: Washer should be equipped with audible alarm that alerts if error code occurs.</p> <p><u>Request</u></p> <p>Page No. 7 of Technical Specification: i.Washer should be equipped with audible alarm that alerts if error code occurs and should also be displayed and printed. Kindly amend the same.</p>	<p>Washer should be equipped with audible alarm that alerts if error code occurs and should also be displayed</p>
	<p>Page No. 7 of Technical Specification: Unit to have LCD display and operating console to have membrane key pad for durability or LCD touch screen display.</p> <p><u>Request</u></p> <p>Page No. 7 of Technical Specification: 2. Unit to have touch screen display and operating console to have membrane key pad for durability or touch screen display. Kindly amend the same.</p>	<p>Tender terms & conditions prevail</p>
	<p>Page No. 7 of Technical Specification: 5. The unit should also have an interface as standard for an optional batch printer.</p> <p><u>Request</u></p> <p>Page No. 7 of Technical Specification: The unit should also have an interface as standard for an optional ink type printer.</p> <p>Ink type printer is better for long storage records of</p>	<p>Batch printer/Ink Printer</p>

	cycles print out. Kindly amend the same.	
	<p>Page No. 8 of Technical Specification: The washer disinfecter shall be supplied with universal rack, 4 level racks for instrument tray, full size instrument tray as well as stop valves, anti-suction device and plastic water trap.</p> <p><u>Request</u></p> <p>Page No. 8 of Technical Specification: The washer disinfecter shall be supplied with universal rack, 4 level racks (3 DIN trays/Level) / 6 level racks (2DIN trays/Level) for instrument tray, full size instrument tray as well as stop valves, anti-suction device and plastic water trap.Kindly amend the same.</p>	4 -6 Levels racks
	5. PLASMA/ H2O2 /LOW TEMPERATURE STRILIZER (Double door)-120-150 L	
	<p>Page No. 8 of Technical Specification: Sterilizer process should be suitable for sterilization of medical devices like flexible endoscopes, rigid endoscopes- both single channel and also dual channel and non lumen, metal, nonmetal heat & moisture sensitive instruments, like defib paddles etc. The sterilizer process must have maximum material device manufacturers' recommendations from major endoscopic equipment manufacturers.</p> <p><u>Request</u></p> <p>Page No. 8 of Technical Specification: 1. Sterilizer process should be able to process materials sensitive to temperatures above 50 deg C and suitable for sterilization of medical devices like rigid endoscopes-both single channel and also dual channel and non lumen, metal, nonmetal heat & moisture sensitive instruments, like defib paddles etc. The sterilizer process must have maximum material device manufacturers' recommendations from major endoscopic equipment manufacturers.</p> <p>We request you to kindly delete sterilization for flexible endoscope as it requires high level disinfection.</p>	Tender terms & conditions prevail.
	<p>Page No. 8 of Technical Specification: 11. Sterilization should be validated using US-FDA/European CE approved Chemical Indicators and Self-Contained Biological indicators with 24 hour read out time.</p> <p><u>Request</u></p> <p>Page No. 8 of Technical Specification: It should be in built Biological incubator & Reader. Kindly add in the specification.</p>	Tender terms & conditions prevail
	<p>Page No. 8 of Technical Specification: 12. Should be able to run on Electricity 50 Hz</p>	Tender terms & conditions prevail.

	<p>three phase meeting IEC-60601-1-2 :2001 General Requirements of Safety for Electromagnetic Compatibility or should comply with 89/366/EEC; EMC- directive.</p> <p><u>Request</u></p> <p>Page No. 8 of Technical Specification: 12. Should meet the requirements of 93/42 / EEC, after 2007/47 / EC and the requirements of EN ISO 14937: 2009. Complies with the directives 2004/108 / EC (EMC) and 2006/95 / EC (LVD). It also complies with the product standards CE EN 61010-1:2013, IEC 61010-2040: 2005, IEC 60204-1: 2010, EN 61326-1: 2013 and IEC 60601-1-2: 2001.</p> <p>Kindly amend the same.</p>	
	<p>Page No. 8 of Technical Specification: 13. Each Sterilizer should be supplied complete with accessories like One no. six Vial incubator(220V), 6 no.s instrument trays of three different sizes with Lids.</p> <p><u>Request</u></p> <p>Page No. 8 of Technical Specification: Kindly add: It should be in built Biological incubator & Reader. Kindly add the same.</p>	Tender terms & conditions prevail.
	<p>Page No. 8 of Technical Specification: 14. Should quote same make consumables having EPA-US/ CE as mentioned below : a H2O2 Sterilant 59% - Cassette or Cup= for 100 load cycles, b Chemical Indicator Strip (for putting inside single item packs)= 2000 strips (for approx.. 100 load cycles), c Biological Indicator Vials = 100 no.s</p> <p><u>Request</u></p> <p>Page No. 8 of Technical Specification: 14. Should quote same make consumables having EPA-US/ CE as mentioned below : a H2O2 Sterilant 58% - Cassette or Cup= for 100 load cycles, b Chemical Indicator Strip (for putting inside single item packs)= 2000 strips (for approx.. 100 load cycles), c Biological Indicator Vials = 100 no.s</p> <p>Should be not more than 58 % and should uses cartridges containing 12 hydrogen capsules each. Each capsule SHOULD contains 2 ml of 58% hydrogen peroxide. According to the type of material loaded inside the chamber, each cartridge will always ensure a number of sterilization cycles ranging between 6 and 12.</p> <p>Kindly amend the same.</p>	Tender terms & conditions prevail.
	<p>Page No. 8 of Technical Specification: Item No. 6 - ULTRASONIC CLEANER (40 L)</p>	Tender terms & conditions prevail.

	<p><u>Request</u></p> <p>Page No. 8 of Technical Specification: Item No. 6 - ULTRASONIC CLEANER (45 - 50 L) Kindly amend the same.</p>	
	<p>Page No. 8 of Technical Specification: The units should be a compact free-standing bench model, with a built-in tank manufactured from high-quality (316/304) 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. <u>Request</u></p> <p>Page No. 8 of Technical Specification: a. The units should be a compact free-standing bench model, with a built-in tank manufactured from high-quality 316L 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. Kindly amend the same.</p>	Tender terms & conditions prevail.
	<p>Page No. 8 of Technical Specification: c. The tank should be made of solid stainless steel (316/304). <u>Request</u></p> <p>Page No. 8 of Technical Specification: c. The tank should be made of solid stainless steel 316L. Kindly amend the same.</p>	Tender terms & conditions prevail.
	<p>f. Capacity should be 40 L <u>Request</u></p> <p>f. Capacity should be 45 – 50 L. Kindly amend the same.</p>	Capacity should be 40L – 50L
	<p>Page No. 9 of Technical Specification Item No. 8 – Drying Cabinet Inner chamber should be made up of stainless steel and outer chamber should be of epoxy painted CRCA sheets <u>Request</u></p> <p>Page No. 9 of Technical Specification Should be completely AISI 304L is better for aesthetic & easy cleaning without contamination. Kindly amend the same.</p>	Inner chamber should be made up of stainless steel and outer chamber should be of epoxy painted CRCA sheets/SS-304
	<p>Page No. 9 of Technical Specification 5. Capacity-275L <u>Request</u></p> <p>Page No. 9 of Technical Specification</p>	Capacity – 275-300 L or

	<p>5. Capacity-300L.</p> <p>Page No. 10 of Technical Specification Item No. 13 – Wash Stations with 2 Sinks for Dirty Area Size Approx. (LxWxH): 2000x900x700 mm (whd) with sink sizes of 40x500x250mm (wdh)</p> <p><u>Request</u> Page No. 10 of Technical Specification Item No. 13 – Wash Stations with 2 Sinks for Dirty Area</p> <p>Kindly note that in BOQ size has been mentioned 2000x750x850. We request you to kindly amend as per technical specification.</p>	<p>Size Approx. (LxWxH): 2000x900x700 mm (whd) with sink sizes of 40x500x250mm (wdh)</p>
	<p>Page No. 12& 13 of Technical Specification: Item No. 20 - Modular Sterilizing Basket Size : 585x395x195 Item No. 21 – Modular Sterilizing Basket Size : 585x395x100</p> <p><u>Request</u> Page No. 12& 13 of Technical Specification: Item No. 20 - Modular Sterilizing Basket Size : 600 x 300 x 290</p> <p>Kindly note that Specification of Modular Sterilizing Basket asked in tender is as per SPRI standard Size while Sterilizer has been asked as per STU standard. We request you to kindly amend the size as per STU.</p>	<p>Modular Sterilizing Basket Size :585x395x100/600 x300x290mm</p>
	<p>Furniture Items</p> <p>All CSSD Furniture items should be accepted with $\pm 10\%$ deviations.</p> <p>Kindly amend the same.</p>	<p>All CSSD Furniture items should be accepted with $\pm 10\%$ deviations.</p>

All other terms & conditions remain unchanged.

Sr. Chief General Manager -I, HSCC (I) Ltd.
For and behalf of Principal, IGMC, Shimla