HSCC/SES/CSSD/LHMC/2022 Date: 09.12.2022

All Bidders

Amendment-III

Subject: Execution including Supply, Installation, Testing & Commissioning of CSSD at LHMC-New Delhi

Tender No: HSCC/SES/CSSD/LHMC/2022 Date: 27.10.2022

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.	Bidders' Queries	Reply
1.	**Item no. 01** **Horizontal Sterilizer 750-800 Ltr. With Accessories** **Processing capacity per cycle should be 10 STU of 600x300x300mm** It should be fully automatically controlled double door Steam Sterilizer and should be horizontal in size with pre and post-vacuum treatment having chamber capacity of approx. 750 - 800 liters carrying 10 STU's per cycle. The sterilizer should have inbuilt electric Steam Generator and vacuum pump. The sterilizer should have double door pneumatically operated vertical sliding doors. Pneumatic door cylinder should in stainless steel for eliminating the risk for particles which can be a problem when the door is operated via chains that has been lubricated. **Steam Generator:** The sterilizer should have an inbuilt steam generator of adequate capacity. It should be mounted under the sterilizer chamber & should be made of SS316L. The steam generator pressure vessel should be made of stainless steel. The sterilizer should be equipped with dual water connections for different water quality for cooling water and steam generator. All connecting pipes and valves shall be made of good quality stainless steel. Process valves are should be pneumatic. Chamber should be mounted on a framework which should have adjustable feet.	Tender terms & conditions prevail.

	Vacuum Pump: The Sterilizers should have a high capacity efficient liquid ring vacuum pump. It should be mounted on vibration isolator for quiet operation. It should be connected to condensers to assist air removal. It should also have low water level alarm to protect it from dry run. Disposable air filter (HEPA) should be provided for filtering the atmospheric air before entering in the chamber. The filter separation efficiency should be higher than 99.99% H14 for particle size less than 0.3μm **AFTER SALES SERVICE:** After-sales-service/maintenance shall be provided by the manufacturer from factory trained engineer. **<u>Amendment Request:</u>** **1. Horizontal Sterilizer 800 Ltr. Or more With Accessories** **Processing capacity per cycle should be 12 STU of 600x300x300mm.** It should be fully automatically controlled double door Steam Sterilizer and should be horizontal in size with pre and post-vacuum treatment having chamber capacity of approx. **800 liters Or more** carrying **12 STU's per cycl**e. The sterilizer should have inbuilt electric Steam Generator and vacuum pump. The sterilizer should have double door **pneumatically/ electrically** operated vertical sliding doors. **In case** Pneumatic door cylinder should in stainless steel for eliminating the risk for particles which can be a problem. **Steam Generator:** The sterilizer should have an inbuilt steam generator of adequate capacity. It should be mounted under the sterilizer chamber & should be made of SS316L. The steam generator pressure vessel should be made of stainless steel. The sterilizer should be equipped with dual water	

	connections for different water quality for cooling water and steam generator. All connecting pipes and valves shall be made of good quality stainless steel. Process valves are should be **pneumatic/ electric**. Chamber should be mounted on a framework which should have adjustable feet. **Vacuum Pump:** The Sterilizers should have a high capacity efficient liquid ring vacuum pump. It should be mounted on vibration isolator for quiet operation. It should be connected to condensers to assist air removal. It should also have low water level alarm to protect it from dry run. Disposable air filter (HEPA) should be provided for filtering the atmospheric air before entering in the chamber. The filter separation efficiency should be higher than 99.99% **H14/H13** for particle size less than 0.3µm **AFTER SALES SERVICE:** After- sales-service/maintenance shall be provided by the **manufacturer/ bidder** from factory trained engineer.	
2.	Item no. 02 **Horizontal Sterilizer 100 TO 150 Ltr. With Accessories** **Processing capacity per cycle should be 1.5 STU of 600x300x300mm** **(a) Door:** The sterilizer supplied should be an single door with vertical sliding movement along with door safety features. **(b) Construction:** 1. **Chamber**: The chamber should be made of solid, high quality 316Ti 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. A stainless steel mesh strainer protects the drain port from blockage by debris. The chamber is mounted on a stainless steel framework with height adjustable feet. 2. **Surface Treatment**: The internal	Tender terms & conditions prevail. b (1)- The chamber should be made of solid, high quality 316Ti/ 316L Stainless steel.

	surface is glass bead blast polished for high quality smooth finish to facilitate cleaning. The resultant surface is polished to less than 0.8 μm which is highly protected against corrosion. The internal corners are rounded to aid cleaning. 5. **Steam Generator**: Sterilizer should have inbuilt steam generator with heating elements not directly exposed to water there by increasing their life. It should be mounted under the sterilizer chamber & should be made of 316 quality stainless steel. The steam generator should have integrated energy storing system helpful in sterilization of heavy loads in less time **(c) PIPES VALVES & COMPONENTS:** Pipes and valves should be made up of copper, Teflon and brass. The hoses should be made of Teflon or rubber. **(e) CONTROL SYSTEM:** 1. The control system should be microprocessor based PLC system specially design for sterilization applications. It should show all the process parameters as well as should have the graphical representation. Apart from main PLC based control system the sterilizer should also have additional independent monitoring & documentation system which constantly cross check the safety systems & time according to EN285 & EN 13445 standards. 2. Five password access levels (0-4) are provided to control access/operation of the machine preventing unauthorized access. These access levels should be customizable. The control system should have CPU processor with battery back-up, Digital input/output controls, analog measuring inputs & COM ports for printer & PC connectivity **(f) TEMPERATURE AND PRESSURE SENSORS:** 1. The sterilizer should have at least 2 temperature sensors one at chamber drain & in Jacket while it should also have 1 pressure sensor in chamber. **(K) VACUUM PUMP:**	

	High capacity water ejector type vacuum pump for removal of air within the chamber should be provided & mounted on vibration isolator for quite operations. It should be connected to series of condensers to assist air removal & protect it from high temperatures. It should also have low water level alarm to protect it from dry run. **(m)** It should meet following Directive and standards **ENISO / USFDA/BIS** **<u>Amendment Request:</u>** **2. Horizontal Sterilizer 70 Ltr. Or more With Accessories** **Processing capacity per cycle should be 01 STU of 600x300x300mm** **(a) Door:** The sterilizer supplied should be a single door with **vertical sliding / hinged door** along with door safety features. For a small steam sterilizer hinged may also please be allowed as it will not use more space while operation. 1. **Chamber**: The chamber should be made of solid, high quality **316Ti/ 316L** Stainless steel. **The chamber should ensure the temperature uniformity in chamber.** The chamber floor is slightly sloped towards an internal drain to facilitate drainage. A stainless steel mesh strainer protects the drain port from blockage by debris. The chamber is mounted on a stainless steel framework with height adjustable feet. 2. **Surface Treatment**: The internal surface is **glass bead/ ceramic** blast polished for high quality smooth finish to facilitate cleaning. The resultant surface is polished to **at least 1.25 µm** which is highly protected against corrosion. The internal corners are rounded to aid cleaning. 5. **Steam Generator**: Sterilizer should have inbuilt steam generator with heating elements not directly exposed to water there by increasing their life.	

	It should be mounted under the sterilizer chamber & should be made of 316 quality stainless steel. The steam generator should have integrated **energy storing system/** **Customer specific program** helpful in sterilization of heavy loads in less time **(c) PIPES VALVES & COMPONENTS:** Pipes and valves should be made up of **copper/ Teflon /brass/ SS**. The hoses should be made of Teflon or rubber. 1. The control system should be microprocessor based PLC system specially design for sterilization applications. It should show all the process parameters as well as should have the graphical representation. Apart from main PLC based control system the sterilizer should also have additional independent monitoring & documentation system which constantly cross check the safety systems & time according to EN285 & **EN 13445/17665** standards. 2. Minimum **four password access levels** are provided to control access/operation of the machine preventing unauthorized access. These access levels should be customizable. The control system should have CPU processor with battery back-up, Digital input/output controls, analog measuring inputs & COM ports for printer & PC connectivity 1. The sterilizer should have at least **2 temperature sensors/ double transducer system**. **(K) VACUUM PUMP:** High capacity water **ejector/ ring** type vacuum pump for removal of air within the chamber should be provided & mounted on vibration isolator for quite operations. It should be connected to series of condensers to assist air removal & protect it from high temperatures. It should also have low water level alarm to protect it from dry run. **(m)** It should meet following Directive and standards USFDA/ European CE Certificate Directive 93/42/EEC on Medical	

	Devices (MDD), PED Directive 2014/ 68/EU, ISO 9001:2015, EN ISO 13485:2016	
3.	Item no. 03 **TABLE TOP STERILIZER** **d) Quality System Compliance:** Sterilizer should comply the quality systems as per ISO 9001:2000, EN ISO 13485:2003, ISO 14001 **f) Types of Cycles Process:** Table Top Sterilizer should be equipped with B process, N-process as per latest EN 13060. Proof of declaration of conformity. **g) Chamber:** should be made of S.S.316Ti & should comply the Pressure Equipment Directive (PED) & EN 13445 norms. • Chamber should have minimum 10 years warranty or should confirm 44- 50,000 process minimum life. • Chamber should have working pressure 2.2 bar & design pressure up to 3.8 bar. • Chamber should have Stress & Fatigue analysis reports for material & construction of the pressure vessel. • Chamber should be equipped with electrically heated jacket for preheating on standby mode. **h) Door Design:** Should have horizontal sliding door with silicon rubber gasket to withstand temperature up to 140°C & 2560 kg pressure. **n) Alarms:** Automatic process checking & failure correction should be possible by the control system. The range of alarm should include Temperature & pressure sensor failure, phase time-out, doors not properly closed, power failure (less than 10 sec should be ignored), continuous self checking of all the safety devices, low water level etc. All the alarms should be audio-visual. **<u>Amendment Request:</u>** **d) Quality System Compliance:** Sterilizer should comply the quality systems as per ISO 9001:2000, **EN ISO 13485:2003/ ISO 14001**	Page 6 of 29 Specs 3 TABLE TOP STERILIZER d) Sterilizer should comply the quality systems as per ISO 9001:2000, EN ISO 13485:2003/ ISO 14001 g) Chamber: Should be made of S.S. 316Ti/316 & should comply the Pressure Equipment Directive (PED) & EN 13445 norms h) Tender terms & conditions prevail. n) Tender terms & conditions prevail.

	f) Types of Cycles Process: Table Top Sterilizers should be equipped with B-process as per latest International standards. Flash / Custom cycle / S-Class as per the latest EN 13060. Proof of declaration of conformity. 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. Kindly specify the same in the Addition Specification Parameter that only B-Process system should be quoted. So the requested amendment may please be accepted and for quality procurement. **g) Chamber:** • should be made of S.S.316Ti & should comply the Pressure Equipment Directive (PED) & EN 13445 norms. • Chamber should have minimum 10 years warranty or should **confirm 18000 process minimum life**. • Chamber should have working pressure 2.2 bar & design pressure up to 3.8 bar. • Chamber should have Stress & Fatigue analysis reports for material & construction of the pressure vessel. • Chamber should be equipped with electrically heated jacket for preheating on standby mode. **h) Door Design:** Should have **horizontal sliding/ Hinged** door with silicon rubber gasket to withstand temperature up to 140°C & **2560 kg/ 2.4 bar** pressure. **n) Alarms:** Automatic process checking & failure correction should be possible by the control system. The range of alarm should include Temperature & pressure sensor failure, phase time-out, doors not properly closed, **power failure (less than 10 sec should be ignored)/ continues monitoring** , continuous self checking of all the safety devices,	

	low water level etc. All the alarms should be audio-visual. We would like to request you to kindly amend the point as requested since system should have real time monitoring of power failure and no alarm should be ignored.	
4.	Item no. 04 **Washer Disinfector with Accessories** **Chamber Capacity:** Operational Volume should be minimum 250 to 300 Lts. Washer Disinfector should be able to accommodate 6 level or more cart to process 12 DIN trays per cycle. The chamber should be made of **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.** **Standards & codes;** • **BIS or** • MDR 2017/745/EU Medical Device Regulation • MD 2006/42/EC Machinery Directive (Safety) • EMC 2014/30/EU Electromagnetic Compatibility Directive • IEC/UL/CSA 61010-1 Safety requirements for electric equipment • IEC/UL/CSA 61010-2-040 Safety requirements for Washer Disinfector and Sterilizers • ETL Certified: tested by an OSHA accredited test lab for safe use • EN/ISO 15883 Parts 1,2,5,6 & 7 Machine and Process design • ANSI/AAMI ST15883 Part 1 & 2 Machine and Process design • WEEE 2012/19/EU Waste Electrical and Electronic Equipment Directive • REACH 1907/2006/EU Registration, Evaluation, Authorization and Restriction of Chemical substances. • RoHS 2011/65/EU+ 2015/863/EU - Restrictions of Hazardous Substances (Electrical products) **Washer should have following features:**	Page 7 of 29 Specs 4 Washer Disinfector with Accessories Chamber Capacity: Operational Volume should be minimum 250 - 300 Lts. or more Washer Disinfector should be able to accommodate 6 level or more cart to process 12 DIN trays per cycle. Standards & codes; • WEEE 2012/19/EU Waste Electrical and Electronic Equipment Directive - Deleted • REACH 1907/2006/EU Registration, Evaluation, Authorization and Restriction of Chemical substances. - Deleted • RoHS 2011/65/EU+ 2015/863/EU - Restrictions of Hazardous Substances (Electrical products) – Deleted Dosing Pumps: The washer should have 3 dosing pump for process chemicals, instrument lubricants & enzymatic cleaners.

	• Injection wash carts should be automatically connect to water and drying air in order to clean and dry the inside of the tubular instrument. The washer should be equipped with dual circulation pump operating intermittently for utility saving and better cleaning efficiency. **<u>Amendment Request:</u>** **Chamber Capacity:** Operational Volume should be minimum 250 to 300 Lts. Washer Disinfector should be able to accommodate 6 level or more cart to process 12 DIN trays per cycle. The chamber should be made of **S.S. 316L quality** with **electro polished/ mechanical** 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.** Standards & Norms: • Should be US FDA/ European CE certified 4 digit notified body. Manufacturer should be ISO 13485:2003/ EN ISO 15883/ IS0 9001 • Injection wash carts should be automatically connect to water and drying air in order to clean and dry the inside of the tubular instrument. The washer should be equipped **with dual circulation pump or minimum pump flow rate 626 l/min** operating intermittently for utility saving and better cleaning efficiency.	Accessories: The washer should be supplied with six level general instrument wash cart to process 12 DIN trays per cycle & loading/unloading trolleys if needed.
5.	Item No. 05 **Low Temperature Plasma Sterilizer** **Operational volume 150 - 175 Liters** a) Should provide simple and fast sterilization of surgical instruments at low temperature using Hydrogen Peroxide Gas Plasma sterilization technology. Plasma generation should be uniform inside the sterilization chamber using a RF Generator for the effective removal of H2O2 from sterilized items and to	Tender terms & conditions prevail.

	compliment the sterilization process. c) The chamber should have usable volume of 150 to 175 litres. The chamber should be made of 316L grade stainless steel. d) The sterilizer should be equipped with automatic vertical sliding door technology. f) Should have total sterilization cycle time of 30-60 min. i) The unit should have facility to increase H2O2 contraction from 59 % to up to 90 % or above to increase the speed and efficacy of the sterilization process. s) Sterilizer should conform to safety & quality standards with proper certifications as per BIS/US FDA/ European CE. Standards EN ISO 13485, EN ISO 9001, ISO 14937 validated sterilization cycles and full CE (EMC EN 60601-1-2, LVD IEC 61010-2-040, and LVD IEC 61010-1) certification **<u>Amendment Request:</u>** **Operational volume 120 Liters or More** a) Should provide simple and fast sterilization of surgical instruments at low temperature using Hydrogen Peroxide Gas Plasma sterilization technology. Plasma generation should be uniform inside the sterilization chamber using a **RF Generator/ Latest Technology** for the effective removal of H2O2 from sterilized items and to compliment the sterilization process. RF energy is older technology and now the latest technologies are available for better efficacy. c) The chamber should have usable volume **of 120 litres or more**. The chamber should be made of 316L grade stainless steel. 120 liters of usable volume can accommodate the various length devices in one go leading to save the operational cost further the robotic instruments and other. So the same may please be amended.	

	d) The sterilizer should be equipped with automatic **vertical sliding/ hinged** door technology **with door sensor** f) Should have total sterilization cycle time of **30-60 min. (±5 min.)** i) The unit should have facility to increase H2O2 contraction from **50- 60%** to increase the speed and efficacy of the sterilization process. s) Sterilizer should conform to safety & quality standards with proper certifications as per BIS/US FDA/ European CE. Standards **EN ISO 13485/ EN ISO 9001**, ISO 14937 validated sterilization cycles and full CE (EMC EN 60601-1-2, LVD IEC 61010-2-040, and LVD IEC 61010-1) certification	
6.	Item no. 08 **LOW TEMPERATURE STEAM FORMALDEHYDE**: **May please be deleted** Since you have already asked for 4 nos. of big steam sterilizer, 2 nos. of small steam sterilizer and Low temperature plasma sterilizer so there is no need for Low temperature steam formaldehyde in CSSD. Also you may see that in many procurement tenders of CSSD by HSCC and By HITES under MoHFW there was no provisions for this equipment, we can share the tender also on request. Moreover, if the authority still want to keep the LTSF then the same should be with lower capacity model along with the requested amendment (attached Separate sheet) to make it generalize in nature for healthy participation. However we still recommend keeping this item shall be clear wastage of money & space in the CSSD.	Tender terms & conditions prevail.
7.	**LOW TEMPERATURE STEAM FORMALDEHYDE**: **HORIZONTAL DOUBLE DOOR LTSF Sterilizer Capacity 550 to 600 Litres** Fully automatic Microprocessor controlled Horizontal LTSF Sterilizer, with pre and post Vacuum treatment and with Loading Equipment having chamber capacity	Tender terms & conditions prevail.

	of **550 to 600 litres**. The sterilizer should have inbuilt electric Steam Generator. The sterilizer should be combination unit which can run both Steam and LTSF process. **A. DOOR:** The sterilizer should have double doors with fully automatic vertical sliding movement with each door actuated by pneumatically operated dual cylinders along with door safety features. **C. CONSTRUCTION**: a) Chamber & Doors: The chamber, doors and jacket 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 should be slightly sloped towards an internal drain to facilitate drainage. A stainless steel mesh strainer protects the drain port from blockage by debris. The chamber should be mounted on a stainless steel framework with height adjustable feet. b) Insulation: The sterilizer jacket and doors should be completely insulated with 50 to 80 mm chloride free mineral wool thereby keeping the autoclave cool on the outside. The insulation should be completely encased in removable rigid aluminium sheet housing. c) Steam Generator: The sterilizer should have an inbuilt steam generator of adequate capacity. It should be mounted under the sterilizer chamber & should be made of SS316L. d) Automatic blow down & degassing of the steam generator should be available as standard. e) The steam generator should have insulation of up to 50 mm thick chloride free mineral wool with rigid aluminium sheet housing. **D. LOADING/UNLOADING** System: Sterilizer should be supplied with one shelf rack with shelfs (carriage) and two fixed height loading/unloading trolleys. **E. PIPES VALVES & COMPONENTS:** a) The piping system should be made of S.S. quality. All the process valves should be stainless steel & should be pneumatically operated piston valves	

	for longer trouble free operations. All the non-standard components should be non-proprietary & should be easily sourced. All the hot pipes should be properly insulated. Only the safety valves should be made of brass. **H. CONTROL SYSTEM & OPERATING PANEL**: **b)** The Control System is operated via 10" or bigger Color touch screen on both loading and unloading side, as a default the operator should have access to select cycle, start cycle & to close door. The unloading side should be equipped with control for opening and closing the door. **I. TEMPERATURE AND PRESSURE SENSORS**: a) The sterilizer should have at least 2 temperature sensors and it should also have 2 pressure sensors. **J. ALARMS**: c) The range of alarms should include i. Chamber High Pressure ii. Low Water level in generator iii. Generator high pressure iv. Chamber PT 100 Temperature sensor error v. Generator high temperature Water Pump operation time out. **K. CYCLE DOCUMENTATION AND NETWORK COMMUNICATION:** The Control system should continuously cross check the sterilizer safety system and the limits set as per EN 285 Standards. **M. Formalin Injection**: The sterilizing agent for low temperature cycles should be stored in liquid state in a single dose bottle. The concentration of formalin solution should be approximately 34 to 38%. The formalin consumption per cycle should be approximately 300 ml solution per cycle. A needle in the bottle holder should puncture the sealed bottle. If the sterilent is not fully used, the bottle should be	

	completely and safely emptied at the end of the process and should be ready for recycling. **N. AVAILABLE CYCLES:** The Sterilizer should be equipped with following Pre-programmed cycles Programs include: ❖ 55° C Formalin Process ❖ 65°C Formalin Process ❖ 80°C Formalin Process ❖ 134°C Steam Sterilization Process ❖ 121°C Steam Sterilization Process ❖ Bowie and Dick test Leak rate test Jacket cooling. Cooling process for forced adaption to low temperature preconditions the average cycle time for Low Temperature mode should be close to 5 hours. **DIRECTIVES & STANDARDS**: The Sterilizer should meet following Directive and Standards Sterilization: Steam Sterilizer–Large Sterilizer-EN 285 for Large Autoclaves EN 14180 + A2 Sterilizers for medical purposes -LTSF Sterilizers ISO 25424:2009 Sterilization - Development, validation and routine control LTSF Sterilization CE - Medical Device Directive – MDD 93/42 EEC as amended by Directive 2007/47/EC or USFDA/BIS Pressure Equipment Directives: PED97/23 EC Low Voltage Directive – 2006/95/EC EMC Directive2004/108/EC ISO 9001:2000 Quality Management Systems-Requirements EN ISO 9001:2008 ISO 13485:2003 (Quality Systems for Medical Devices) **<u>Amendment Request:</u>** **HORIZONTAL DOUBLE DOOR** **LTSF Sterilizer Capacity 100 Litres or more** Fully automatic Microprocessor controlled Horizontal LTSF Sterilizer, with pre and post Vacuum treatment and with Loading Equipment having chamber capacity of **100 litres or more**. The sterilizer should have inbuilt electric Steam Generator. The sterilizer should be combination unit which can run	

	LTSF process between temperatures 55°C to 75°C. Since you have already asked for 4 big and 2 small steam sterilizer, so this may please be keep for Low temperature application only. **A. DOOR:** The sterilizer should have double doors with fully automatic **vertical sliding/ hinged** movement with each door actuated by **pneumatically operated dual cylinders/ electrically operated** along with door safety features. a) Chamber & Doors: The chamber, doors and jacket 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 should be slightly sloped towards an internal drain to facilitate drainage. A stainless steel mesh strainer protects the drain port from blockage by **debris/ effective flushing of steam**. The chamber should be mounted on a stainless steel framework with height adjustable feet. b) Insulation: The sterilizer jacket and doors should be completely insulated thereby keeping the autoclave cool on the outside. The insulation should be completely encased in removable rigid aluminium sheet housing. **c) May please be deleted** As this point is relevant to machine steam sterilizer process and we have requested above to keep the specification only for Low Temp. Application. So the same may please be removed. **D. LOADING/UNLOADING (OPTIONAL)** System: Sterilizer should be supplied with one shelf rack with shelfs (carriage) and two fixed height loading/unloading trolleys. a) The piping system should be made of **copper/ Teflon /brass/ SS** quality. All the process valves should be stainless steel & should be **pneumatically operated piston valves/ electrically operated** for longer trouble free operations. All the non-standard components should be non-proprietary & should be easily sourced. All the hot pipes should be properly insulated. Only the	

	safety valves should be made of brass. **b)** The Control System is operated via **7" or bigger** Color touch screen on both loading and unloading side, as a default the operator should have access to select cycle, start cycle & to close door. The unloading side should be equipped with control for opening and closing the door. **a) The sterilizer should have temperature sensors and it should also have pressure sensors.** c) The range of alarms should **include/ relevant Alarms** i. Chamber High Pressure ii. Low Water level in generator iii. Generator high pressure iv. Chamber PT 100 Temperature sensor error v. Generator high temperature Water Pump operation time out. The Control system should continuously cross check the sterilizer safety system and the limits set as per **EN 14180 Standards.** EN 285 standard is for Steam sterilizer, so the point may please be allowed as requested. **M. Formalin Injection**: The sterilizing agent for low temperature cycles should be stored in liquid state in a single dose bottle. **Low sterilization media consumption per cycle (2 L of 2 % FO solution + 2 L of demineralized water).** A needle in the bottle holder should puncture the sealed bottle. If the sterilent is not fully used, the bottle should be completely and safely emptied at the end of the process and should be ready for recycling. **N. AVAILABLE CYCLES:** The Sterilizer should be equipped with following Pre-programmed cycles Programs include: ❖ 55° C Formalin Process ❖ 60°C Formalin Process 75°C Formalin Process **May please be deleted**	

	This point is specific to one company so the same may please be removed. **DIRECTIVES & STANDARDS**: The Sterilizer should meet following Directive and Standards Sterilization: DIN EN 14180, DIN EN 61326-1, DIN EN 61010-1, DIN EN 61010-2-040, DIN EN 62304, DIN EN 62366-1.	
8.	Item no. 08 **DRYING CABINET** The capacity of the Drying Cabinet should be approximately 250 to 300L. The unit should have capacity to process 36 hoses in the same drying cycle. The air should be heated by an electric heating element controlled and regulated by a precision thermostat. The cabinet should be provided with a built-in electric precipitator for cleaning of incoming air. Separation efficiency should be 94 – 100% for particle size 0.01 – 5 µm. **<u>Amendment Request:</u>** The capacity of the Drying Cabinet should be **approximately 200 L or more** The unit should have capacity to process **36 hoses/ Minimum 2 no. of** shelves in the same drying cycle. The air should be heated by an electric heating element controlled and regulated by a precision thermostat. The requested company specific point may please be amended as requested to enable the wider participation	Tender terms & conditions prevail.
9.	Item no. 12 **Rotary heat Sealer** should provide validated sealing (as per DIN 58953T7 with manufacturing certificate) of sterilization bags and clear-view pouches (paper/plastic laminate). These through feed-type sealers should be microprocessor-controlled for highest capacity and ease of operation. The	Item no. 12 **1. Rotary heat Sealer** should complies to validated sealing (**as per DIN 58953T7/ ISO 11607**) of sterilization

	ergonomically design should be tilted forward for increased user convenience and space saving installation. The sealers should be built and tested in accordance with EU safety norms. The sealer housing should be powder-coated and the control panel is of the flat membrane type, for easy cleaning **<u>Amendment Request:</u>** should complies to validated sealing (**as per DIN 58953T7/ ISO 11607**) of sterilization bags and clear-view pouches (paper/plastic laminate). These through feed-type sealers should be microprocessor-controlled for highest capacity and ease of operation. The ergonomically design should be tilted forward for increased user convenience and space saving installation. The sealers should be built and tested in accordance with EU safety norms. The sealer housing should be powder-coated and the control panel is of the flat membrane type, for easy cleaning	bags and clear-view pouches (paper/plastic laminate). These through feed-type sealers should be microprocessor-controlled for highest capacity and ease of operation. The ergonomically design should be tilted forward for increased user convenience and space saving installation. The sealers should be built and tested in accordance with EU safety norms. The sealer housing should be powder-coated and the control panel is of the flat membrane type, for easy cleaning.
10.	**1. Wash Stations with 2 sinks : Area : Dirty** **Size (LxWxH) : 2000x750x850 mm** • Corners should be curved to a 65 mm radius for easy cleaning. **<u>Amendment Request:</u>** • **Corners should be curved to a 45 mm radius approx. for easy cleaning.**	**1. Wash Stations with 2 sinks : Area : Dirty** **Size (LxWxH) : 2000x750x850 mm** • Corners should be curved to a 45mm - 65 mm radius for easy cleaning.
11.	**5. Control & Packing Table with two Shelves** **Area : Clean** **Size (LxWxH) : 2000x1400x900 mm** • The single workplace table should have 700 mm wide worktop and a double workplace should have1400 mm worktop. **<u>Amendment Request:</u>** The single workplace table should have 700 mm wide worktop and a **total** double workplace should have 1400 mm worktop.	**5. Control & Packing Table with two Shelves** **Area : Clean** **Size (LxWxH) : 2000x1400x900 mm** • The single workplace table should have 700 mm wide worktop and a total double workplace should have 1400 mm worktop.
12.	**13. Pass Box** **Area : Dirty to Clean supply & Sterile Issue** **Size : 600x600x600mm, internal** • The chamber should consist of two manually openable doors, and a Plexiglas-and-aluminium construction on a	Tender terms & conditions prevail.

	stainless steel bottom plate, which is equipped with four adjustable legs for easy assembly and adjustment. **<u>Amendment Request:</u>** • The chamber should consist of two manually openable doors, and construction on a stainless steel bottom plate, which is equipped with four adjustable legs for easy assembly and adjustment.	
13.	**15. Closed Transport Trolley** **Area : Sterile Store to OT Size : 1400x750x1260 mm** • A trolley for sterile goods handling where higher than normal dust protection is required, e.g. short transports between hospital buildings. Suitable for handling baskets or containers with a total capacity of 9 STU (1 STU = 600 x 300 x 300 mm) on three solid, removable shelves (3 x 3 STU). Trolley should be fitted with large stainless steel wheels (Ø 160 mm) for easier maneuverability. Amendment Request: • A trolley for sterile goods handling where higher than normal dust protection is required, e.g. short transports between hospital buildings. Suitable for handling baskets or containers with a total capacity of 9 STU (1 STU = 600 x 300 x 300 mm) on three solid, **two removable shelves** **and one fixed** (3x 3 STU). • Trolley should be fitted with large stainless steel **wheels / padded wheels** (Ø 160 mm) for easier maneuverability. May please amended to avoid noisy movement.	Tender terms & conditions prevail.
14.	**Furniture Items for CSSD** **± 10% tolerance may please be allowed in sizes for furniture items** A minimum tolerance of 10% may please be allowed.	**Furniture Items for CSSD** Tolerance limit ±5%
15.	**Item no. 24** **24. TURNKEY WORKS** Page 29 Essential consumables for operation of CSSD shall be	Tender terms & conditions prevail.

	provided by the hospital. Non-Essential consumables viz packing materials, extra containers/trays for operation of CSSD shall be provided by the Hospital. Hospital will provide consumables Like Biological Indicator and Chemical Indicator, Detergent, Neutralizer, Disinfectant, H2O2 Sterilant Cassette and Tyvek Reels. **<u>Amendment Request:</u>** Essential consumables for operation of CSSD shall be provided by the hospital. Non-Essential consumables viz packing materials, extra containers/trays for operation of CSSD shall be provided by the Hospital. Hospital will provide consumables Like Biological Indicator and Chemical Indicator, Detergent, Neutralizer, Disinfectant, H2O2 **Sterilant Cassette/ bottle**, **Air Filter, Paper Roll** and Tyvek Reels. **Please specify Area of CSSD and also kindly provide the drawing (CAD file), please specify on which floor the CSSD is located. Please share the contact details of the person who could facilitate of the CSSD site. Please specify the tonnage capacity of air conditioning.**	
16.	**Also, kindly extend the tender for at least 10-15 days from the date of publishing the amendment to provide sufficient time to quote the tender.**	Last date of submission of tender is already extended till 14.12.2022.
17.	**Vol04_TechSpecs,** **Page no. 1, Point no. 1** **CSSD EQUIPMENT: 1. Horizontal Sterilizer 750-800 Ltr. With Accessories.** Processing capacity per cycle should be 10 STU of 600x300x300mm It should be fully automatically controlled double door Steam Sterilizer and should be Horizontal in size with pre and post-vacuum treatment having chamber capacity of approx. 750 - 800 liters carrying 10 STU's per cycle. Amendment Request: **CSSD EQUIPMENT: 1. Horizontal Sterilizer 650-700 Ltr. With Accessories.** Processing capacity per cycle should be 10 STU	Tender terms & conditions prevail.

	It should be fully automatically controlled double door Steam Sterilizer and should be Horizontal in size with pre and post-vacuum treatment having chamber capacity of approx. 650 - 700 liters carrying 10 STU's per cycle. It is informed that Sterilizer should be 650 -700 Litres, which is enough for useable volume for 10 STU, Since the capacity is always measured in STU according to the EN standards and ltr capacity is always defer one OEM to other, while measuring the actual capacity it is only depend on to accommodate the STU of the capacity, therefore ltr capacity should be deleted and 10 STU capacity should be considered or amend 650 to 700 with 10 STU. Every manufacturer have own model with different capacities and dimensions, hence every manufacturer will offer relevant model with their capacity and dimension as technical specification of the tender. Kindly amend the point as requested.	
18.	**Request for adding:** **WATER SAVING SYSTEM:** Sterilizer should have system for water saving to limit the water usage to save up to 50% compare to the normal cycle. The sterilizer should be supplied with RO system. It is informed that Water saving system not mentioned for this sterilized, hence kindly add the same for better productivity of the product.	Tender terms & conditions prevail.
19.	**Page no. 3, Point no. 1** The Sterilizer should meet following Directive and standards BIS/ MDR, EN 285: 2015 for large sterilizers / EN ISO 13485/ EN ISO 17665-1 / EN ISO 14001:2015 / EN 61326-1/ IEC 61326-1 / EN/IEC 61010-2 – 040 & Part 2-040 / 93/42/EEC Medical Device Directive as amended by Directive 2007/47/EC / Machinery Directive2014/35/EC Low Voltage Directive2014/30/EC EMC Directive2014/68/EU Pressure Equipment Directive2011/65/EU RoHS2 Restriction of Hazardous Substances Directive 2012/19/EU WEEE2 Waste Electrical and Electronic Equipment Directive. **<u>Amendment Request:</u>**	Tender terms & conditions prevail.

	The Sterilizer should meet following Directive and standards MDR, EN 285: 2015 for large sterilizers / EN ISO 13485/ EN ISO 17665-1 / EN ISO 14001:2015 / EN 61326-1/ IEC 61326-1 / EN/IEC 61010-2 – 040 & Part 2-040 / 93/42/EEC Medical Device Directive as amended by Directive 2007/47/EC / Machinery Directive2014/35/EC Low Voltage Directive2014/30/EC EMC Directive2014/68/EU Pressure Equipment Directive2011/65/EU RoHS2 Restriction of Hazardous Substances Directive 2012/19/EU WEEE2 Waste Electrical and Electronic Equipment Directive. Kindly amend the same for durability and productivity of the product.	
20.	**Page no. 3, Point no. 2** **2. Horizontal Sterilizer 100 TO 150 Ltr. With Accessories** Processing capacity per cycle should be 1.5 STU of 600x300x300mm **<u>Amendment Request:</u>** Processing capacity per cycle should be 1.5 STU Every manufacturer have their own model with different capacities and dimensions, hence every manufacturer will offer relevant/suitable model with their capacity and dimension as technical specification of the tender. Kindly amend the point as requested.	Tender terms & conditions prevail.
21.	**Page no. 4, Point no. m** **(m)** It should meet following Directive and standards **ENISO / USFDA/BIS** **<u>Amendment Request:</u>** It should meet following Directive and standards ENISO / USFDA/ European CE with notified body 4 digit no. Kindly amend the same for durability and productivity of the product.	Tender terms & conditions prevail.
22.	**Page no. 6, Point no. 3. TABLE TOP STERILIZER**	

	c) Chamber Size : The sterilizer should have Rectangular chamber with approx. dimensions 220 X 200 X 345 mm. for maximum processing capacity per charge. **<u>Amendment Request:</u>** **c**) Chamber Size: The sterilizer should have Rectangular chamber for maximum processing capacity per charge. Every manufacturer have their own model with different capacities and dimensions, hence every manufacturer will offer relevant/suitable model with their capacity and dimension as technical specification of the tender. Kindly amend the point as requested.	**Page no. 6, Point no. 3. TABLE TOP STERILIZER** **c**) Chamber Size : The sterilizer should have Rectangular chamber with approx. dimensions 220 X 200 X 345 mm. for maximum processing capacity per charge.
23.	**Page no. 7, Point no. 3.** d) Quality System Compliance: Sterilizer should comply the quality systems as per ISO 9001:2000, EN ISO 13485:2003, ISO 14001 **<u>Amendment Request:</u>** Quality System Compliance: Sterilizer should comply the quality systems as per ISO 9001:2000 and EN ISO 13485:2003 EN ISO 14001 standard is not required for manufacturers of CSSD Equipments, hence kindly amend the same for durability and productivity of the product.	**Page no. 7, Point no. 3.** d) Quality System Compliance: Sterilizer should comply the quality systems as per ISO 9001:2000, EN ISO 13485:2003/ ISO 14001
24.	**Page no. 7, Point no. 3.** e) Quality Standards: Sterilizer should comply with the quality standards of Medical Device Directive (MDD), EN 13060 or US FDA/BIS. **<u>Amendment Request:</u>** Quality Standards: Sterilizer should comply with the quality standards of Medical Device Directive (MDD), EN 13060 or US FDA/CE from Notified body with 4 digit no.. Kindly amend the same for durability and productivity of the product. 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 delete the same.	Tender terms & conditions prevail.

25.	**Page no. 8, Point no. 4. Washer Disinfector with Accessories** Standards & codes; • BIS or • MDR 2017/745/EU Medical Device Regulation • MD 2006/42/EC Machinery Directive (Safety) • EMC 2014/30/EU Electromagnetic Compatibility Directive • IEC/UL/CSA 61010-1 Safety requirements for electric equipment • IEC/UL/CSA 61010-2-040 Safety requirements for Washer Disinfector and Sterilizers • ETL Certified: tested by an OSHA accredited test lab for safe use • EN/ISO 15883 Parts 1,2,5,6 & 7 Machine and Process design • ANSI/AAMI ST15883 Part 1 & 2 Machine and Process design • WEEE 2012/19/EU Waste Electrical and Electronic Equipment Directive • REACH 1907/2006/EU Registration, Evaluation, and Authorization and Restriction of Chemical substances. • RoHS 2011/65/EU+ 2015/863/EU - Restrictions of Hazardous Substances (Electrical products) **<u>Amendment Request:</u>** Standards & codes; • CE from notified body with 4 digit no. • MDR 2017/745/EU Medical Device Regulation • MD 2006/42/EC Machinery Directive (Safety) • EMC 2014/30/EU Electromagnetic Compatibility Directive • IEC/UL/CSA 61010-1 Safety requirements for electric equipment • IEC/UL/CSA 61010-2-040 Safety requirements for Washer Disinfector and Sterilizers • EN/ISO 15883 Parts 1,2,5,6 & 7 Machine and Process design • ANSI/AAMI ST15883 Part 1 & 2 Machine and Process design • WEEE 2012/19/EU Waste Electrical and Electronic Equipment Directive • REACH 1907/2006/EU Registration, Evaluation, and Authorization and Restriction of Chemical substances. • RoHS 2011/65/EU+	**Page no. 8, Point no. 4. Washer Disinfector with Accessories** Standards & codes; • WEEE 2012/19/EU Waste Electrical and Electronic Equipment Directive - Deleted • REACH 1907/2006/EU Registration, Evaluation, Authorization and Restriction of Chemical substances. - Deleted • RoHS 2011/65/EU+ 2015/863/EU - Restrictions of Hazardous Substances (Electrical products) – Deleted

	2015/863/EU - Restrictions of Hazardous Substances (Electrical products) 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 delete the same.	
26.	**Page no. 9, Point no. 5. Low Temperature Plasma Sterilizer Operational volume 150 - 175 Liters** s) Sterilizer should conform to safety & quality standards with proper certifications as per BIS/US FDA/ European CE. Standards EN ISO 13485, EN ISO 9001, ISO 14937 validated sterilization cycles and full CE (EMC EN 60601-1-2, LVD IEC 61010-2-040, and LVD IEC 61010-1) certification **<u>Amendment Request:</u>** s) Sterilizer should conform to safety & quality standards with proper certifications as per US FDA/ European CE from notified body with 4 digit no.. Standards EN ISO 13485, EN ISO 9001, ISO 14937 validated sterilization cycles and full CE (EMC EN 60601-1-2, LVD IEC 61010-2-040, and LVD IEC 61010-1) certification Kindly amend the same for durability and productivity of the product. 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 delete the same.	Tender terms & conditions prevail.
27.	**Page no. 10, Point no.6. LOW TEMPERATURE STEAM FORMALDEHYDE:** **HORIZONTAL DOUBLE DOOR LTSF Sterilizer Capacity 550 to 600 Litres** CE - Medical Device Directive – MDD 93/42 EEC as amended by Directive 2007/47/EC or USFDA/BIS **<u>Amendment Request:</u>** CE - Medical Device Directive – MDD 93/42 EEC as amended by Directive 2007/47/EC or USFDA/ European CE from notified body with 4 digit no. Kindly amend the same for durability and productivity of the product.	Tender terms & conditions prevail.

	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 delete the same.	
28.	**Page no. 10, Point no. 7. Ultrasonic Cleaner 40 to 50 Litres** h) Ultrasonic cleaner should be European CE /US FDA/BIS certified. **Amendment Request:** Ultrasonic cleaner should be European CE Declaration of conformity /US FDA certified. As you aware that Ultrasonic cleaner is Class I product, hence third party certification not required for the same, kindly amend the same.	Tender terms & conditions prevail.
29.	**Page no. 16, Point no. 12. Rotary heat Sealer** Should provide validated sealing (as per DIN 58953T7 with manufacturing certificate) of sterilization bags and clear-view pouches (paper/plastic laminate). **Amendment Request:** Should provide validated sealing of sterilization bags and clear-view pouches (paper/plastic laminate). DIN 58953T7 with manufacturing certificate not required for Rotary heat sealer machine, it is used for sterilization paper packing rolls and pouches which are consumables. Hence, kindly amend the same.	**Page no. 16, Point no. 12. Rotary heat Sealer** Item no. 12 **1. Rotary heat Sealer** should complies to validated sealing (as per DIN 58953T7/ ISO 11607) of sterilization bags and clear-view pouches (paper/plastic laminate).
30.	Request for adding Accepted 5% ± Tolerance in CSSD equipment and furniture. **Amendment Request:** Every manufacturer have their own model with different capacities and dimensions, hence every manufacturer will offer relevant/suitable model with their capacity and dimension as technical specification of the tender. Kindly amend the point as requested.	5% ± Tolerance in furniture items.
31.	Volume-I, Page no. 3, Period of Completion: 4 Months We request the period of completion should be 5 months. The Project is large and arranging quantity of material	Tender terms & conditions prevail.

	takes time and resources. In the running site, we practically face many hindrances, problem in working. The equipment are BIS/US FDA, CE, UL certified. We hereby request to kindly increase the completion schedule to 5 months.	
32.	Volume-III, Page no. SCC-36, Clause no. 21.0 Terms of Payment For purposes of estimating the contract value of works executed for certificate of payment, the following norms shall be followed: 1) 70 % of the BOQ contract rates on delivery of equipments/items at site after inspection and passing on pro-rata basis. 2) 20% of BOQ contract rates on satisfactory take over certificate by client after erection and installation, testing and commissioning of equipments/items on pro-rata basis. 3) 10 % of BOQ contract rates after successful completion of trial run of 30 days from the date of handover to the client. We request, the payment terms should be amended as: 1) 75% of the BOQ contract rates on delivery of equipments at site after inspection and passing on pro-data basis. 2) 15% of BOQ contract rates after erection and installation, 3) 10% of BOQ contract rates after successful trial run of 30 days to M/s HSCC/Client on pro-data basis. Please appreciate, as soon as the work order is received, the contractor has to initiate necessary actions for successful execution of the work order. Among the very important, Contractor need to place order to the respective suppliers along with 100% payment because supplier will not wait till the completion of the project. Here it is worthwhile to say that contractor do not get 75% payment as 2.5% amount gets hold for Security from Running Bill; 1% towards Labour Cess; 3% towards Performance Bank Guarantee, 18% towards GST & in case of delay in supply then liquidated damages. After going through all this in the netshell a contractor gets very less percentage of amount at the initial stage. It is just a eye wash that 70-75% payment will be released on pro-rata basis. Initial payment is the lifeline to the contractors, which gives relief up to some extent.	Tender terms & conditions prevail.

	With regard to 15% payment, please be noted that commissioning and handing over has no difference. After commissioning by our experience, most of the sites are not ready for handover such as civil work is not complete, hospital staff/Doctors are not available etc etc. Without any fault of contractor, he need to wait for the payment till the handing over takes place. Therefore this payment should be at the time of erection and installation.	
33.	Page 2 of 29 Specs 2 Horizontal Sterilizer 100 TO 150 Ltr. With Accessories The required Horizontal Sterilizer capacity is too less. Only certain manufacturers can produce 100-150 low capacity. Different Manufacturer's produces different capacities. We request to kindly define range from 100-300 Ltr, so that manufacturers who produces slightly higher capacity could also participate.	Tender terms & conditions prevail.
34.	Page 6 of 29 Specs 3 TABLE TOP STERILIZER c) Chamber Size : The sterilizer should have Rectangular chamber with approx dimensions 220 X 200 X 345 mm. for maximum processing capacity per charge g) Chamber: Should be made of S.S.316Ti & should comply the Pressure Equipment Directive (PED) & EN 13445 norms h) Door Design: Should have horizontal sliding door with silicon rubber gasket to withstand temperature up to 140°C & 2560 kg pressure **<u>Amendment Request:</u>** c) We request the chamber should be rectangular/ Cylindrical in shape (as 99% manufacturers produces Cylindrical shape chambers for table top Sterilizer) Only one manufacturer produces rectangular shape, rest of the manufacturer provides cylindrical. g) S.S. 316Ti is Titanium Stabilised Stainless Steel material which is expensive and will raise the project cost.	Page 6 of 29 Specs 3 TABLE TOP STERILIZER c) Chamber should be rectangular with approx dimensions 220 X 200 X 345 mm. for maximum processing capacity per charge g) Chamber: Should be made of S.S. 316Ti/316 & should comply the Pressure Equipment Directive (PED) & EN 13445 norms h) Tender terms & conditions prevail.

	We request the quality of Chamber material should be S.S. 316Ti/316L so that the project cost should remain intact. h) It is mentioned that Horizontal Sliding door; whereas it should be "Automatic Door Closing/ Manual Door Closing" to withstand temperature upto 140 Deg C as Different Manufacturers produces different variants/models.	
35.	Page 7 of 29 Specs 4 Washer Disinfector with Accessories Chamber Capacity: Operational Volume should be minimum 250 to 300 Lts. Washer Disinfector should be able to accommodate 6 level or more cart to process 12 DIN trays per cycle. Standards & codes; • WEEE 2012/19/EU Waste Electrical and Electronic Equipment Directive • REACH 1907/2006/EU Registration, Evaluation, Authorization and Restriction of Chemical substances. • RoHS 2011/65/EU+ 2015/863/EU - Restrictions of Hazardous Substances (Electrical products) Dosing Pumps: The washer should have 4 dosing pump for process chemicals, instrument lubricants & enzymatic cleaners. Accessories: The washer should be supplied with six level general instrument wash cart to process 12 DIN trays per cycle & loading/unloading trolleys if needed.. **<u>Amendment Request:</u>** We request the chamber capacity operational volume should be in the range of 250 to 320 Ltrs as Different Manufacturers produces different variants/models. We request the washer disinfector should be able to accommodate 5 to 6 level or more cart to process 10 to 12 DIN trays per cycle treatment as Different Manufacturers produces different variants/models. We wish to inform that these standards & codes are applicable and in practice in Europe not in India. These three standards have nothing to do with the performance	Page 7 of 29 Specs 4 Washer Disinfector with Accessories Chamber Capacity: Operational Volume should be minimum 250 - 300 Lts. or more Washer Disinfector should be able to accommodate 6 level or more cart to process 12 DIN trays per cycle. Standards & codes; • WEEE 2012/19/EU Waste Electrical and Electronic Equipment Directive - Deleted • REACH 1907/2006/EU Registration, Evaluation, Authorization and Restriction of Chemical substances. - Deleted • RoHS 2011/65/EU+ 2015/863/EU - Restrictions of Hazardous Substances (Electrical products) – Deleted Dosing Pumps: The washer should have 3 dosing pump for process chemicals, instrument

	of the washer, it is mainly meant for the Electronic parts that are to be disposed off after their life is finished. We are using washer disinfector in India and when they shall be condemned or removed it shall be as per Indian Laws. More importantly it doesn't have any relevance with the performance or disposal, as it shall be done in India. It's only to make the things complicated. We request these 3 standards & codes should be deleted as it is not applicable as per Indian conditions. We request a range of 3 to 4 dosing pump for processing chemicals, instument lubricants & enzymatic cleaners should be given as 4 are not required. Different Manufacturers produces different variants/models. More imporantly both will perform the same process. We request the washer should be able to accommodate 5 to 6 level or more cart to process 10 to 12 DIN trays per cycle & loading/unloading trolleys, as Different Manufacturers produces different variants/models.	lubricants & enzymatic cleaners. Accessories: The washer should be supplied with six level general instrument wash cart to process 12 DIN trays per cycle & loading/unloading trolleys if needed.
36.	Page 8 of 29 Specs 5 Low Temperature Plasma Sterilizer i) The unit should have facility to increase H2O2 contraction from 59 % to up to 90 % or above to increase the speed and efficacy of the sterilization process Amendment request: This point is of no meaning as efficacy of plasma sterilizer is very high and at fixed concentration, the cycles are tested again and again and thereafter the Standards are provided by third party. Moreover the cycle time is very fast, so what is the purpose of increase it more with increasing in concentration. This is monopolistic feature and only one company has this feature. Other bidders cannot comply to the specific specifications. It should be broad based or may please be deleted.	Low Temperature Plasma Sterilizer i)The unit should have facility to increase H2O2 contraction from 59 % to up to 90 % or above to increase the speed and efficacy of the sterilization process.
37.	Page 9 of 29 Specs 6 LOW TEMPERATURE STEAM FORMALDEHYDE This is preferably not used in most of the CSSD set up as Steam Sterilizers are main units in CSSD set up. For low	Tender terms & conditions prevail.

	temp, either ETO sterilizers or Plasma Sterilizers are preferred/used. This item is manufactured by 1 -2 manufacturers worldwide and it will increase the tender budget unnessary. ETO/Plasma Sterilizers are used for low temp sterilization. Henceforth, we request this should be deleted.	
38.	Page 13 of 29 Specs 7 Ultrasonic Cleaner 40 to 50 Litres We request Ultrasonic Cleaner should be in the range of 40 to 60 Liters capacity as Different Manufacturers produces different variants/models.	Ultrasonic Cleaner 40 to 60 Litres.
39.	HSCC (I) Ltd. (the Executing Agency)	HSCC (I) Ltd. (the Executing Agency) may be read as HSCC (I) Ltd. (Consultant).
40.	Integrity Pact & Agreement	Revised Integrity Pact & Agreement format is enclosed herewith at Annexure-B and bidder must submit the same duly signed & stamped along with bid documents.

All other terms & conditions remain unchanged.

Sd/-
Director, LHMC, New Delhi

INTEGRITY PACT

To,

…….

……

……

Sub: NIT No. HSCC/SES/CSSD/LHMC/2022 for the work "Execution including Supply, Installation, Testing & Commissioning of CSSD at LHMC-New Delhi"

Dear Sir,

It is here by declared that HSCC is committed to follow the principle of transparency, equity and competitiveness in public procurement.

The subject Notice Inviting Tender (NIT) is an invitation to offer made on the condition that the Bidder will sign the integrity Agreement, which is an integral part of tender/bid documents, failing which the tenderer/bidder will stand disqualified from the tendering process and the bid of the bidder would be summarily rejected.

This declaration shall form part and parcel of the Integrity Agreement and signing of the same shall be deemed as acceptance and signing of the Integrity Agreement on behalf of the HSCC.

Yours faithfully

HSCC (I) Ltd.
For & on Behalf of Director, LHMC, New Delhi

Signature of Bidder

Signature of HSCC

INTEGRITY PACT

To,
HSCC (India) Limited,
E-6(A), Sector 1,
Noida - 201301

Sub: Submission of Tender for the work of "Execution including Supply, Installation, Testing & Commissioning of CSSD at LHMC-New Delhi"

Dear Sir,

I/We acknowledge that HSCC is committed to follow the principles thereof as enumerated in the Integrity Agreement enclosed with the tender/bid document.

I/We agree that the Notice Inviting Tender (NIT) is an invitation to offer made on the condition that I/We will sign the enclosed integrity Agreement, which is an integral part of tender documents, failing which I/We will stand disqualified from the tendering process. I/We acknowledge that THE MAKING OF THE BID SHALL BE REGARDED AS AN UNCONDITIONAL AND ABSOLUTE ACCEPTANCE of this condition of the NIT.

I/We confirm acceptance and compliance with the Integrity Agreement in letter and spirit and further agree that execution of the said Integrity Agreement shall be separate and distinct from the main contract, which will come into existence when tender/bid is finally accepted by HSCC. I/We acknowledge and accept the duration of the Integrity Agreement, which shall be in the line with Article 6 of the enclosed Integrity Agreement.

I/We acknowledge that in the event of my/our failure to sign and accept the Integrity Agreement, while submitting the tender/bid, HSCC shall have unqualified, absolute and unfettered right to disqualify the tenderer/bidder and reject the tender/bid.

Yours faithfully

(Duly authorized signatory of the Bidder)

Signature of Bidder

Signature of HSCC

To be signed by the bidder and same signatory competent / authorized to sign the relevant contract on behalf of HSCC.

INTEGRITY AGREEMENT

This Integrity Agreement is made at ..... on this ..... day of ..... 20.....

BETWEEN

HSCC (India) Limited, as a Consultant represented appointed by LHMC, New Delhi by HSCC (India) Limited (hereinafter referred as the 'Principal', which expression shall unless repugnant to the meaning or context hereof include its successors and permitted assigns)

AND

..... (Name and Address of the Individual/firm/Company) ..... through ..... (Details of duly authorized signatory)..... (Hereinafter referred to as the "Bidder/Contractor" and which expression shall unless repugnant to the meaning or context hereof include its successors and permitted assigns)

Preamble

WHEREAS the Principal has floated the Tender (NIT No. HSCC/SES/CSSD/LHMC/2022) (hereinafter referred to as "Tender/Bid") and intends to award, under laid down organizational procedure, contract for "Execution including Supply, Installation, Testing & Commissioning of CSSD at LHMC-New Delhi".

AND WHEREAS the Principal necessarily requires full compliance with all relevant laws of the land, rules, regulations, economic use of resources and of fairness/transparency in its relation with its Bidder(s) and Contractor(s).

AND WHEREAS to meet the purpose aforesaid both the parties have agreed to enter into this Integrity Agreement (hereinafter referred to as "Integrity Pact" or "Pact"), the terms and conditions of which shall also be read as integral part and parcel of the Tender/Bid documents and Contract between the parties.

AND WHEREAS In order to achieve these goals, the Principal will appoint Independent External

Monitor(s) (IEM(s))) who will monitor the tender process and the execution of the Contract for compliance with the principles mentioned hereinunder

NOW, THEREFORE, in consideration of mutual covenants contained in this Pact, the parties hereby agree as follows and this Pact witnesses as under:

Article 1: Commitment of the Principal

The Principal is committed to follow the principle of transparency, equity and competitiveness in public Procurement.

(1) The Principal commits itself to take all measures necessary to prevent corruption and to observe the following principles:

(a) No employee of the Principal, personally or through family members or through any other channel, will in connection with the Tender, or the execution of the Contract, demand, take a promise for or accept, for self or third person, any material or immaterial benefit which the person is not legally entitled to.

(b) The Principal will, during the Tender process, treat all Bidder(s) with equity and reason. The Principal will, in particular, before and during the Tender process, provide to all Bidder(s) the same information and will not provide to any Bidder(s) confidential/additional information through which the Bidder(s) could obtain an advantage in relation to the Tender process or the Contract execution.

(c) The Principal shall endeavour to exclude from the Tender process any person, whose conduct in the past has been of biased nature.

(2) If the Principal obtains information on the conduct of any of its employees, Contractor(s) and/or bidder(s) which constitutes a criminal offence under the Indian Penal code (IPC)/Prevention of Corruption Act, 1988 (PC Act) or is in violation of the principles herein mentioned or if there be a substantive suspicion in this regard, the Principal will inform the Chief Vigilance Officer and in addition can also initiate disciplinary actions as per its internal laid down policies and procedures.

Article 2: Commitment of the Bidder(s)/Contractor(s)

1. It is required that each Bidder/Contractor (including their respective officers, employees and agents) adhere to the highest ethical standards, and report to the Principal all suspected acts of fraud or corruption or Coercion or Collusion of which it has knowledge or becomes aware, during the tendering process and throughout the negotiation or award of a contract.
2. The Bidder(s)/Contractor(s) commits himself to take all measures necessary to prevent corruption. He commits himself to observe the following principles during his participation in the Tender process and during the Contract execution:

(a) The Bidder(s)/Contractor(s) will not, directly or through any other person or firm, offer, promise or give to any of the Principal's employees involved in the Tender process or execution of the Contract any material or other benefit which he/she is not legally entitled to, in order to obtain in exchange any advantage of any kind whatsoever during the Tender process or during the execution of the Contract.

(b) The Bidder(s)/Contractor(s) will not enter with other Bidder(s) into any undisclosed agreement or understanding, whether formal or informal. This applies in particular to prices, specifications, certifications, subsidiary contracts, submission or non-submission of bids or any other actions to restrict competitiveness or to cartelize in the bidding process.

(c) The Bidder(s)/Contractor(s) will not commit any offence under the relevant IPC/PC Act. Further the Bidder(s)/Contractor(s) will not use improperly, (for the purpose of competition or personal gain), or pass on to others, any information or documents provided by the Principal as part of the business relationship, regarding plans, technical proposals and business details, including information contained or transmitted electronically.

(d) The Bidder(s)/Contractor(s) of foreign origin shall disclose the names and addresses of agents/representatives in India, if any. Similarly Bidder(s)/Contractor(s) of Indian Nationality shall disclose names and addresses of foreign agents/representatives, if any. Either the Indian agent on behalf of the foreign Principal or the foreign Principal directly could bid in a tender but not both. It shall be incumbent on the Indian Agent and the foreign Principal to adhere to the relevant guidelines of the Government of India, issued from time to time regarding availing of services of Indian Agents for Foreign Suppliers. The Bidder(s)/Contractor(s) shall disclose details mentioned in the "Guidelines of Indian Agents of Foreign Suppliers. Also as mentioned in the Guidelines, all the payments made to Indian agent/representatives shall be in Indian Rupees only.

(e) The Bidder(s)/Contractor(s) will, when presenting his bid, disclose any and all payments he has made, is committed to or intends to make to agents, brokers or any other intermediaries in connection with the award of the Contract.

(f) Bidder(s)/Contractor(s) who have signed the Integrity Pact shall not approach the courts while representing the matter to IEM(s) and shall wait for their decision in the matter.

3. The Bidder(s)/Contractor(s) will not instigate third persons to commit offences outlined above or be an accessory to such offences.

4. The Bidder(s)/Contractor(s) will not, directly or through any other person or firm indulge in fraudulent practice, wilful misrepresentation or omission of facts or submission of fake/forged documents in order to induce public official to act in reliance thereof, with the purpose of obtaining unjust advantage by or causing damage to justified interest of others and/or to influence the procurement process to the detriment of the Principal's interests.

5. The Bidder(s)/Contractor(s) will not, directly or through any other person or firm use Coercive Practices (means the act of obtaining something, compelling an action or

influencing a decision through intimidation, threat or the use of force directly or indirectly, where potential or actual injury may befall upon a person, his/ her reputation or property to influence their participation in the tendering process).

Article 3: Consequences of Breach

Without prejudice to any rights that may be available to the Principal under law or the Contract or its established policies and laid down procedures, the Principal/ shall have the following rights in case of breach of this Integrity Pact by the Bidder(s)/Contractor(s) and the Bidder/ Contractor accepts and undertakes to respect and uphold the Principal's absolute right:

1. If the Bidder(s)/Contractor(s), either before award or during execution of Contract or during the validity of the Integrity Pact has committed a transgression through a violation of Article 2 above or in any other form, such as to put his reliability or credibility in question, the Principal at its sole discretion after giving proper opportunity to the Bidder(s)/Contractor(s) shall have powers to disqualify the Bidder(s)/Contractor(s) from the Tender process or terminate/determine the Contract, if already executed or exclude the Bidder/Contractor from future contract award processes for that reason, without prejudice to any other legal rights or remedies available to the Principal under the relevant provisions of the Tender/Contract. The imposition and duration of the exclusion will be determined by the severity of transgression and determined by the Principal. Such exclusion may be forever or for a limited period as decided by the Principal.
2. Forfeiture of EMD/Performance Guarantee/Security Deposit: If the Principal has disqualified the Bidder(s) from the Tender process prior to the award of the Contract or terminated/determined the Contract or has accrued the right to terminate/determine the Contract according to Article 3(1), the Principal apart from exercising any legal rights that may have accrued to the Principal, may in its considered opinion forfeit the entire amount of Earnest Money Deposit, Performance Guarantee and Security Deposit of the Bidder/Contractor.
3. Criminal Liability: If the Principal obtains knowledge of conduct of a Bidder or Contractor, or of an employee or a representative or an associate of a Bidder or Contractor which constitutes a criminal offence within the meaning of IPC/PC Act, or if the Principal has substantive suspicion in this regard, the Principal will inform the same to the Chief Vigilance Officer.

Article 4: Previous Transgression

1. The Bidder/Contractor declares that no previous transgressions occurred in the last 5 years with any other Company in any country confirming to the anticorruption approach or with Central Government or State Government or any other Central/State Public Sector

Enterprises in India that could justify his exclusion from the Tender process.

2. If at any point of time during the Tender Process or after the award of Contract, it is found that the Bidder/Contractor has made an incorrect statement on this subject, he can be disqualified from the Tender process or terminate/determine the Contract, if already executed or action can be taken for banning of business dealings/ holiday listing of the Bidder/Contractor as deemed fit by the Principal.
3. If the Bidder/Contractor can prove that he has resorted / recouped the damage caused by him and has installed a suitable corruption prevention system, the Principal may, at its own discretion, revoke the exclusion prematurely.

Article 5: Equal Treatment of all Bidders/Contractors/Subcontractors

1. The Bidder(s)/Contractor(s) undertake(s) to demand from all subcontractors a commitment in conformity with this Integrity Pact. The Bidder/Contractor shall be responsible for any violation(s) of the principles laid down in this agreement/Pact by any of its Subcontractors/sub-vendors.
2. The Principal will enter into Pacts on identical terms as this one with all Bidders and Contractors.
3. The Principal will disqualify Bidders, who do not submit, the duly signed Pact between the Principal and the bidder, along with the Tender or violate its provisions at any stage of the Tender process, from the Tender process.

Article 6- Duration of the Pact

This Pact begins when both the parties have legally signed it. It expires for the Contractor/Vendor 12 months after the completion of work under the contract or till the continuation of defect liability period, whichever is more and for all other bidders, till the Contract has been awarded.

If any claim is made/lodged during the time, the same shall be binding and continue to be valid despite the lapse of this Pact as specified above, unless it is discharged/determined by the Competent Authority of HSCC.

Article 7- Independent External Monitor(s) (IEM(s))

1. The Principal shall appoint competent and credible Independent External Monitor, nominated by the Central Vigilance Commission, for this pact in case of all works with estimated cost put to tender in excess of Rs.5 crores. The task of the Monitor is to review independently and objectively, the cases referred to it to assess whether and to what extent the parties comply with the obligations under this Integrity Pact.

2. In case of non-compliance of the provisions of the Integrity Pact, the complaint/non-compliance is to be lodged by the aggrieved party with the Nodal Officer only who shall be nominated by the MD, HSCC. The Nodal Officer shall refer the complaint/non-compliance so received by him to the aforesaid monitor.
3. The Monitor is not subject to instructions by the representatives of the parties and performs his/her functions neutrally and independently. The Monitor shall report to MD, HSCC.
4. The Bidder(s)/Contractor(s) accepts that the Monitor shall have the right to access without restriction all project documentation of the Principal including that provided by the Contractor. The Contractor will also grant the Monitor, upon his/her request and demonstration of a valid interest, unrestricted and unconditional access to their project documentation. The Monitor is under contractual obligation to treat the information and documents with confidentiality.
5. As soon as the Monitor notices, or believes to notice, a violation of this agreement, he/she will so inform the Principal and request the Principal to discontinue or take corrective action, or to take other relevant action(s). The Monitor can in this regard submit non-binding recommendations. However, beyond this, the Monitor has no right to demand from the parties that the act in a specific manner and/or refrain from action and/or tolerate action.
6. The Monitor will submit a written report to the MD, HSCC within 4 to 6 weeks from the date of reference or intimation to him/her and, should the occasion arise, submit proposals for corrective actions for the violation or the breaches of the provisions of the agreement noticed by the Monitor.
7. If the Monitor has reported to the MD, HSCC of a substantiated suspicion of an offence under relevant IPC/PC Act, and the MD, HSCC has not, within the reasonable time taken visible action to proceed against such offence or reported it to the Chief Vigilance Officer, the Monitor may also transmit this information directly to the Chief Vigilance Officer.
8. Issues like Warranty/Guarantee etc. shall be outside the purview of the IEMs.
9. The role of the Monitor is advisory and would not be legally binding and is restricted to resolving issues raised by the Bidder/Contractor.
10. The word “Monitor” means Independent External Monitor and includes both singular and plural forms.

Article 8- Other Provisions

1. This Pact is subject to Indian Law, place of performance and jurisdiction is the Registered Office of the Principal, i.e., New Delhi.
2. Changes and supplements as well as termination notices need to be made in writing.
3. If the Bidder/Contractor is a partnership or a consortium, this Pact must be signed by all the partners or by one or more partner holding power of attorney signed by all partners and consortium members. In case of a Company, the Pact must be signed by a representative duly authorized by board resolution.

4. Should one or several provisions of this Pact turn out to be invalid, the remainder of this Pact remains valid. In this case, the parties will strive to come to an agreement to their original intensions.
5. It is agreed term and condition that any dispute or difference arising between the parties with regard to the terms of this Integrity Agreement / Pact, any action taken by the Principal in accordance with this Integrity Agreement/ Pact or interpretation thereof shall not be subject to arbitration.
6. In view of the nature of the Integrity Pact, the Integrity Pact is irrevocable and shall remain valid even if the main tender/contract is terminated till the currency of the Integrity Pact.

Article 9- LEGAL AND PRIOR RIGHTS

All rights and remedies of the parties hereto shall be in addition to all the other legal rights and remedies belonging to such parties under the Contract and/or law and the same shall be deemed to be cumulative and not alternative to such legal rights and remedies aforesaid. For the sake of brevity, both the Parties agree that this Integrity Pact will have precedence over the Tender/Contact documents with regard any of the provisions covered under this Integrity Pact.

IN WITNESS WHEREOF the parties have signed and executed this Integrity Pact at the place and date first above mentioned in the presence of following witnesses:

…….
…….
(For and on behalf of Principal) (For and on behalf of Bidder/Contractor)

WITNESSES:

1 .....
(signature, name and address)

2 .....
(signature, name and address)

Place:
Dated: