

**HSCC (INDIA) LIMITED**  
(A Subsidiary of NBCC (India) Limited)  
(A GOVERNMENT OF INDIA ENTERPRISE)

Dated 29.08.2024

**AMENDMENT-II**

**Project Name: Execution including Design, Supply, Installation, Testing & Commissioning of Special Services at CSSD LHMC-New Delhi.**

**Tender No: HSCC/LHMC/SES/CSSD WORK/2024 dated: 05.08.2024**

This has reference to subject work, the following Amendment may be noted, which shall be treated as a part of the contract to be uploaded along with tender/ bid:

**(I).** The Last date of submission & opening of bids has been extended as follows:

Last date to fill/upload the tender : upto 15:00 hrs. on **04.09.2024**  
through e-Tendering

Date of Opening of bids : on 04.09.2024 at 16:00 hrs.

**(II) Reply to Pre-Bid Queries raised by bidders during pre -bid meeting held on 12.08.2024 at HSCC, Head Office, Noida**

Sr. No.	Vol. No./ Ref./ Description/ Clause No.	As per Tender	Bidder's Query / Request	HSCC Reply/ to be Amended
1.	Horizontal Sterilizer 750-800 Ltr. With Accessories	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	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.	<b>No Change, Shall be as per tender condition</b> (Needed for long term trouble free operation)
	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	Steam Generator: The sterilizer should have an inbuilt steam generator of adequate capacity. It should be mounted under the sterilizer chamber	<b>No Change, shall be as per tender condition</b>

		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.	& 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.	(Pneumatic valves more robust, better for long term trouble free operation)
	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	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	<b>No Change, Shall be as per tender condition</b>
	AFTER SALES SERVICE	After-sales service/maintenance shall be provided by the manufacturer from factory trained engineer	AFTER SALES SERVICE: After sales-service/maintenance shall be provided by the manufacturer/ bidder from factory trained engineer.	<b>No Change, Shall be as per tender condition</b>  <b>To be included</b> (Presence of registered office with GST number of the manufacturer in India is must)
			Added Specification: Manufacturer/ Bidder should have installation of same make in the Indian Market for at least 07 Years	<b>Accepted</b>
2.	Washer Disinfector with Accessories	<b>Chamber Capacity:</b> 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	Chamber Capacity: Operational Volume should be minimum 250 to 300 Lts. Washer Disinfector should be	<b>Accepted</b>

		made of <b>S.S. 316L quality</b> 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 <b>bright light for clear visibility of the washing process.</b>	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 & codes; <ul style="list-style-type: none"> <li>• MDR 2017/745/EU Medical Device Regulation</li> <li>• MD 2006/42/EC Machinery Directive (Safety)</li> <li>• EMC 2014/30/EU Electromagnetic Compatibility Directive</li> <li>• IEC/UL/CSA 61010-1 Safety requirements for electric equipment</li> <li>• IEC/UL/CSA 61010-2-040 Safety requirements for Washer Disinfectors and Sterilizers</li> <li>• ETL Certified: tested by an OSHA accredited test lab for safe use</li> <li>• EN/ISO 15883 Parts 1,2,5,6 &amp; 7, Machine and Process design</li> <li>• ANSI/AAMI ST15883 Part 1 &amp; 2, Machine and Process design</li> <li>• WEEE 2012/19/EU Waste Electrical and Electronic Equipment Directive</li> <li>• REACH 1907/2006/EU Registration, Evaluation, Authorization and Restriction of Chemical substances.</li> <li>• RoHS 2011/65/EU+ 2015/863/EU - Restrictions of Hazardous Substances (Electrical product)</li> </ul>	Standards & Norms:• Should be US FDA/ European CE certified 4 digit notified body. Manufacturer should be ISO 13485:2003/ EN ISO 15883/ ISO 9001	<b>No change</b> Need compliance to latest standards
		• 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.	• 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.	<b>No change</b> (Dual Pump is more efficient for operations and utility consumption)

3.	Low Temperature Plasma Sterilizer	<b>Operational volume 150 - 175 Liters</b>	Usable volume 115 Liters or more	<b>No Change, Shall be as per tender condition</b>
		The chamber should have usable volume of 150 to 175 litres. The chamber should be made of 316L grade stainless steel	c) The chamber should have usable volume of 115 litres or more. The chamber should be made of 316L grade stainless steel.	<b>No Change, Shall be as per tender condition</b>
		The sterilizer should be equipped with automatic vertical sliding door technology.	d) The sterilizer should be equipped with vertical sliding/ hinged door technology with door sensor	<b>No Change, Shall be as per tender condition</b>
		Should have total sterilization cycle time of 30-60 min.	f) Should have smallest sterilization cycle time of 30±5 min. and longest least than 60 min.	<b>Accepted</b>
		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.	i) The unit should have facility to increase H2O2 concentration from 50-60% to increase the speed and efficacy of the sterilization process.	<b>Accepted</b>

		<p>The unit should be mobile, easy to install without any civil / plumbing work &amp; operate in 230V / 430 V (Single phase / Three phase)          Sterilizer should conform to safety &amp; 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</p>	<p>Equipment should be US FDA/ European CE with 4- digit notified body as per amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices and EN ISO 13485 (Medical Device Directive) from a four-digit notified body certificate. The process of the sterilizer has to be fully complied with EN ISO 14937</p>	<p><b>No change, Shall be as per tender condition</b></p>
			<p>Added Specification: Sterilant should be multi-use bottle/ cartridges with minimum 05 nos. cycle in each sterilant bottle/ cartridges. Bidder should specify the no. of cycle.</p>	<p><b>Accepted</b></p>
			<p>Added Specification: Should have installation of atleast 20 for quoted OEM in reputed Govt. Institute of India.</p>	<p><b>Tender terms and condition prevail</b></p>
4.		<p>LOW TEMPERATURE STEAM FORMALDEHYDE:</p>	<p>May please be deleted</p>	<p><b>No Change, Shall be as per tender condition</b></p>
5.	<p>DRYING CABINET</p>	<p>The capacity of the Drying Cabinet should be approximately 250 to 300L</p>	<p>The capacity of the Drying Cabinet should be approximately 300 L or more</p>	<p><b>No Change, Shall be as per tender condition</b></p>

		The air should be heated by an electric heating element controlled and regulated by a precision thermostat. The cabinet should be provided with a builtin electric precipitator for cleaning of incoming air. Separation efficiency should be 94 – 100% for particle size 0.01– 5 µm.	The air should be heated by an electric heating element controlled and regulated by a precision thermostat.	<b>No Change, Shall be as per tender condition</b>
6.	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 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	should complies to validated sealing (as per DIN 58953T7/ ISO 11607) of sterilization bags and clear-view pouches (paper/plastic laminate). These through feedtype 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	<b>Accepted</b>
7.	<b>CSSD FURNITURE ITEMS:</b>	<b>1. Wash Stations with 2 sinks :</b> <b>Area : Dirty Size (LxWxH) : 2000x750x850 mm</b>		
		• Corners should be curved to a 65 mm radius for easy cleaning.	• Corners should be curved to a 45 mm radius approx. for easy Cleaning.	<b>No Change, Shall be as per tender condition</b>
		<b>5. Control &amp; Packing Table with two Shelves Area : Clean Size (LxWxH) : 2000x1400x900 mm</b>		
		• The single workplace table should have 700 mm wide worktop and a double workplace should have 1400 mm worktop	• The single workplace table Should have 700 mm wide worktop and a total double workplace should have 1400 mm worktop.	<b>Accepted</b>
		<b>13. Pass Box</b> <b>Area : Dirty to Clean supply &amp; Sterile Issue</b> <b>Size : 600x600x600mm, internal</b>		
		• The chamber should consist of two manually openable doors, and a Plexiglas-and-aluminium construction on a stainless steel bottom plate, which is Equipped with four adjustable legs for easy assembly and adjustment.	• The chamber should consist of two manually openable doors, and construction on a stainless steel bottom plate, which is equipped with four	<b>Accepted</b>

			adjustable legs for easy Assembly and adjustment.	
		<b>15. Closed Transport Trolley</b> <b>Area : Sterile Store to OT</b> <b>Size : 1400x750x1260 mm</b>		
		<ul style="list-style-type: none"> <li>• 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).</li> </ul>	<ul style="list-style-type: none"> <li>• 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)</li> </ul>	<b>Accepted</b>
		<ul style="list-style-type: none"> <li>• Trolley should be fitted with large stainless steel wheels (Ø 160 mm) for easier manoeuvrability</li> </ul>	Trolley should be fitted with large stainless steel wheels / padded wheels (Ø 160 mm) for easier manoeuvrability.	<b>No Change, Shall be as per tender condition</b>
		<b>Furniture Items for CSSD</b>	± 10% tolerance may please be allowed in sizes for furniture items	<b>Accepted</b>
		<b>Addition of different sizes of Closed Sterilization Containers</b>		<b>Tender terms and conditions prevail</b>
8.	Eligibility & Commercial Terms	Manufacturer's Authorization: Bidder must ensure and meet all the terms of tender including technical specifications. The lowest responsive bidder shall submit the Manufacturer's Authorization letter as per format enclosed at Annexure-A of Technical Specifications of tender documents along with quality certificates as per the standards mentioned in the tender documents for all the equipment/items.	Manufacturer Authorization: Eligible bidders quoting as an Indian Agent should submit a Manufacturer's Authorization letter as per format enclosed at Annexure-A from the Foreign Principal / Manufacturer, with name of manufacturing company for major products quoted by them as per given format as detailed below: A. Exclusive Items 1 Horizontal Sterilizer 2 Washer Disinfecter 3 Plasma/ H2O2/ Low Temperature Sterilizer B. Non-Exclusive Like: 1. Ultrasonic Cleaner 2. Heat Sealing Machine 3. Drying Cabinet For other small items Manufacturer authorization should not be required. Additional terms : List of All the Consumables required to run the equipment's	<b>Tender terms and conditions prevail.</b>

			should be submitted along with the Price Bid which will be freeze Till the warranty + CAMC period.  BOQ: Revised Item List/ BOQ Enclosed.	
		CMC Table I CMC for 2nd Year-2% CMC for 3rd Year-2.20% CMC for 4th Year-2.42% CMC for 5th Year-2.46%	CMC Table I CMC for 2nd Year-5% CMC for 3rd Year-5.25% CMC for 4th Year-5.50% CMC for 5th Year-5.75%	<b>Tender Terms and conditions prevail.</b>
9.	<b>Vol-IV TECHNICAL SPECIFICATION</b>	Point No. 1. Horizontal Sterilizer 750-800 Ltr. With Accessories Qty: 04 Nos. 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.	Horizontal Sterilizer 650- 700 Ltr. with Accessories. Processing capacity per cycle should be 10 STU. 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.	<b>No Change, Shall be as per tender condition, (need balance of space available and processing capacity)</b>
			Request for adding: Water Saving System: Sterilizer should have system for water saving to limit the water usage to save upto 50% compare to the normal cycle. The sterilize should be supplied with RO System,	<b>Water Saving System: Sterilizer should have system for water saving to limit the water usage. The sterilizer should be supplied with RO System,</b>
10.	<b>Vol-IV TECHNICAL SPECIFICATION</b>	<b>Point No. 1. Horizontal Sterilizer 750-800 Ltr. With Accessories Qty: 04 Nos</b> <b>The Sterilizer should meet following Directive and standards</b> 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 Directive 2014/30/EC EMC Directive 2014/68/EU Pressure Equipment Directive2011/65/EU RoHS2 Restriction of Hazardous Substances Directive2012/19/EU WEEE2 Waste Electrical and Electronic Equipment Directive.	The Sterilizer should meet following Directive and standards MDD, 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 Directive 2014/30/EC EMC Directive 2014/68/EU Pressure Equipment	<b>No Change, Shall be as per tender condition (Need compliance to latest standards)</b>
11.	<b>Vol-IV TECHNICAL SPECIFICATION</b>	Point No. 2 Washer Disinfector with Accessories Qty -04 Nos. Standards & codes; • MDR 2017/745/EU	CE from notified body with 4 digit no. • MD 2006/42/EC Machinery Directive (Safety)	<b>No Change, Shall be as per tender condition (Need)</b>



		<p>Medical Device Regulation</p> <ul style="list-style-type: none"> <li>• MD 2006/42/EC</li> </ul> <p>Machinery Directive (Safety)</p> <ul style="list-style-type: none"> <li>• EMC 2014/30/EU</li> </ul> <p>Electromagnetic Compatibility Directive</p> <ul style="list-style-type: none"> <li>• IEC/UL/CSA 61010-1</li> </ul> <p>Safety requirements for electric equipment</p> <ul style="list-style-type: none"> <li>• IEC/UL/CSA 61010-2-040</li> </ul> <p>Safety requirements for Washer Disinfectant and Sterilizers</p> <ul style="list-style-type: none"> <li>• ETL Certified: tested by an OSHA accredited test lab for safe use</li> <li>• EN/ISO 15883 Parts 1,2,5,6 &amp; 7 Machine and Process design</li> <li>• ANSI/AAMI ST15883 Part 1 &amp; 2 Machine and Process design</li> <li>• WEEE 2012/19/EU Waste Electrical and Electronic Equipment Directive</li> <li>• REACH 1907/2006/EU</li> </ul> <p>Registration, Evaluation, Authorization and Restriction of Chemical substances.</p> <ul style="list-style-type: none"> <li>• RoHS 2011/65/EU+ 2015/863/EU – Restrictions of Hazardous Substances (Electricalproducts) BIS</li> </ul>	<ul style="list-style-type: none"> <li>• EMC 2014/30/EU Electromagnetic Compatibility Directive</li> <li>• IEC/UL/CSA 61010-1 Safety requirements for electric equipment</li> <li>• IEC/UL/CSA 61010-2-040 Safety requirements for Washer Disinfectant and Sterilizers</li> <li>• EN/ISO 15883 Parts 1,2,5,6 &amp; 7 Machine and Process design</li> <li>• ANSI/AAMI ST15883 Part 1 &amp; 2 Machine and Process design</li> <li>• WEEE 2012/19/EU Waste Electrical and Electronic Equipment Directive</li> </ul>	<p><b>compliance to latest standards)</b></p>
12.	Vol-IV TECHNICAL SPECIFICATION	<p>Point No. 3. Low Temperature VH2O2 Sterilizer Qty: 01</p> <p>Operational volume 150 – 175 Liters</p> <p>Safety &amp; 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</p>	<p>safety &amp; quality Standards with proper certifications as per 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</p>	<p><b>No Change, Shall be as per tender condition (BIS cannot be removed)</b></p>
13.	Vol-IV TECHNICAL SPECIFICATION	<p>Point No. 4. LOW TEMPERATURE STEAM FORMALDEHYDE Qty : 01unit HORIZONTAL DOUBLE DOOR LTSF Sterilizer Capacity 550 to 600 Litres</p> <p><b>DIRECTIVES &amp; STANDARDS:</b></p> <p>The Sterilizer should meet following Directive and standards Sterilization: Steam Sterilizer–Large Sterilizer-EN 285 for Large Autoclaves BIS/EN 14180 + A2 Sterilizers for medical purposes -LTSF Sterilizers</p> <p>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 Pressure Equipment Directives: PED97/23 EC</p> <p>Low Voltage Directive – 2006/95/EC/ EMC Directive2004/108/EC</p>	<p>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</p> <p>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</p>	<p><b>No Change, Shall be as per tender condition</b></p>

		/ISO 9001:2000 Quality Management Systems Requirements EN ISO 9001:2008 ISO 13485:2003 (Quality Systems for Medical Devices)/BIS	Pressure Equipment-Directives: PED97/23 EC Low Voltage Directive – 2006/95/EC/ EMC Directive2004/108/EC/ISO 9001:2015 Quality Management Systems Requirements EN ISO 9001:2015 ISO 13485:2016 (Quality Systems for Medical Devices)/	
14.	Vol-IV TECHNICAL SPECIFICATION	Point No. 5. Ultrasonic Cleaner 40 to 50 Litres Qty. : 02 Nos Ultrasonic cleaner should be BIS / European CE /US FDA certified.	Ultrasonic cleaner should be European CE Declaration of conformity /US FDA certified.	<b>Ultrasonic cleaner should be European CE Declaration of conformity /US FDA certified/BIS</b>
15.	Vol-IV TECHNICAL SPECIFICATION	Point No. 10. Rotary heat Sealer Qty : 02 Nos It should provide validated sealing (as per DIN 58953T7 with manufacturing certificate) of sterilization bags and clear-view pouches (paper/plastic laminate).	Should provide validated sealing of sterilization bags and clear-view pouches (paper/plastic laminate).	<b>No Change, Shall be as per tender condition</b>
		Request for adding	Request for adding Accepted 5% + Tolerance in CSSD equipment and Furniture.	<b>10% tolerance clause accepted</b>
		Request for adding	Horizontal Sterilizer 100 TO 150 Ltr. With Accessories. Complete as per technical specifications.- 2 Nos.	<b>No Change, Shall be as per tender condition (Already installed)</b>
		Request for adding	TABLE TOP STERILIZER Complete as per technical specifications.-3 Nos.	<b>No Change, Shall be as per tender condition</b>
		Request for adding	DRYING CABINET.: Complete as per technical specifications.-2 nos	<b>No Change, Shall be as per tender condition</b>

**(II).** The validity of Bid Security/ Earnest Money Deposit (EMD) to be submitted by the bidders with their bid in the form of Bank Guarantee (BG) shall be considered from the original due date of bid submission i.e., from **20.08.2024**.

All other terms & conditions remain unchanged. Prospective bidders are advised to regularly visit through HSCC e-tender portal <https://hsccltd.co.in> & HSCC website <http://www.hsccltd.co.in> as corrigendum/amendments etc. if any, will be notified on this portal only and no separate advertisement will be made for this.

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GM (Proc.)/ HOD  
HSCC (India) Ltd.