HSCC/SES/CSSD/LHMC/2022 Date: 04.01.2023

All Bidders

Amendment-VI

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.	1. Horizontal Sterilizer 750-800 Ltr. With Accessories. (Pg. 3 of Technical Specifications} The Sterilizer should meet following Directive and standards: BISI MDR, WEEE2 Waste Electrical and Electronic Equipment Directive.) **Amendment Request:** 1. "BIS/MDR" has been specified in the technical specifications. Please be aware that this will lead to sub-standard products being delivered to the institution. "MDR" in itself is nothing. **It** must be mentioned as following: ''MDR European CE issued by a four digit notified body as per (EU) n.2017/745" OR "European CE Certified by a four digit notified body as per Medical Device Directive 93/42/EEC" for manufacturers who have not upgraded to "MDR" because their CE certification from the old medical device directive is still valid or they're undergoing up gradation to MDR. Since public money is being spent on such high cost	Regulation (EU) 2017/745 (MDR) is a regulation of the European Union on the clinical investigation and sale of medical devices for human use. It repeals Directive 93/42/EEC (MDD). It includes changes in device classification and device scope, stricter oversight of manufacturers by Notified Bodies and other major changes that will increase the safety and efficacy of the equipment's. The regulation was published on 5 April 2017 and came into force on 25 May 2017. Originally approved medical devices were given a transition time of three years to meet new requirements. The date by which the Regulation was to be fully implemented by replacing the previous directives was originally defined as 26 May 2020. Following the international health emergency COVID-19, deadline was postponed the by one year to 26 May 2021. Therefore, it is

	sterilizing machines, it is essential that the HSCC should not leave any loopholes with respect to the certifications mentioned in the tender. i. No tenders in the past in India or recent HITES tender have ever mentioned the WEEE2 Waste Electrical and Electronic Equipment Directive (2012/19/EU). This has been specifically instated to favor Med Freshe Pvt. Ltd. In addition to above, no regulatory authority including The Central Pollution Control Board, Central Drugs Standard Control Organization (CDSCO), National Accreditation Board of Hospitals (NABH) or any other medical regulation body in India has recommended requirements for this particular directive.	imperative that all companies of good repute should comply with European Union Medical Device Regulation 2017/745. Amendment to read as **''BIS/MDR European CE issued by a four digit notified body as per (EU) n.2017/745"** WEE – WEEE 2012/19/EU Waste Electrical and Electronic Equipment Directive – has been deleted in the Amendment.
2.	1. Horizontal Sterilizer 100 TO 150 Ltr. With Accessories (Pg. 5 of Technical Specifications) "(m) It should meet following Directive and standards ENISO / USFDA /BIS" **Amendment Request:** This particular clause in tender will lead to sub-standard products being delivered to the institution i.e. ENISO / USFDA/ BIS" Ideally, the following certifications should be instated for clarity and quality: i) UL List ed 2) MDR European CE issued by a four digit notified body as per (EU) n.2017/745 or European CE Certified by a four digit notified body as per Medical Device Directive 93/42/EEC for manufacturers who have not upgraded to "MDR" because their CE certification from the old medical device directive is still valid. 3) ISO 13485 4) BIS	Regulation (EU) 2017/745 (MDR) is a regulation of the European Union on the clinical investigation and sale of medical devices for human use. It repeals Directive 93/42/EEC (MDD). It includes changes in device classification and device scope, stricter oversight of manufacturers by Notified Bodies and other major changes that will increase the safety and efficacy of the equipment's. The regulation was published on 5 April 2017 and came into force on 25 May 2017. Originally approved medical devices were given a transition time of three years to meet new requirements. The date by which the Regulation was to be fully implemented by replacing the previous directives was originally defined as 26 May 2020. Following the international health emergency COVID-

	"ENISO/USFDA/BIS" is hogwash and is illogical. Some of these certifications can be obtained in India in less than Rs. *6,000/-*	19, deadline was postponed the by one year to 26 May 2021. Therefore, it is imperative that all companies of good repute should comply with European Union Medical Device Regulation 2017/745. Amendment to read as **''BIS/MDR European CE issued by a four digit notified body as per (EU) n.2017/745"** WEE – WEEE 2012/19/EU Waste Electrical and Electronic Equipment Directive – has been deleted in the Amendment.
3.	Washer Disinfector with Accessories (Pg. 7 of Technical Specifications) • 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) **Amendment Request:** A. The manner in which these technical specifications have been mentioned is a confused mixture. Kindly specify European, American and Indian standards distinctly so that bidders can clearly understand which one to follow and propose.	Regulation (EU) 2017/745 (MDR) is a regulation of the European Union on the clinical investigation and sale of medical devices for human use. It repeals Directive 93/42/EEC (MDD). It includes changes in device classification and device scope, stricter oversight of manufacturers by Notified Bodies and other major changes that will increase the safety and efficacy of the equipment's. The regulation was published on 5 April 2017 and came into force on 25 May 2017. Originally approved medical devices were given a transition time of three years to meet new requirements. The date by which the Regulation was to be fully implemented by replacing the previous directives was originally defined as 26 May 2020.

	B. "MDR 2017/745/EU" should be written as "MDR European CE issued by a four digit notified body as per (EU) n.2017/745 / European CE Certified by a four digit notified body as per Medical Device Directive 93/42/EEC*"* for clarity and quality control. Some European manufacturers have not upgraded to MDR yet because their European CE certification from previous medical device directive is still valid and they are engaged in CE certification process upgrading to MDR. It will be very unfair to rule out manufacturers under going up gradation. B. In addition to above: 1) WEEE 2012/19/EU Waste Electrical and Electronic Equipment Directive & 2) REACH 1907/2006/EU Registration, Evaluation, Authorization and Restriction of Chemical substances have never been mentioned in CSSD tenders in India or recent HITES AIIMS tenders. No regulatory authority including The Central Pollution Control Board, Department of Chemicals and Petrochemicals Central Drugs Standard Control Organization (CDSCO), National Accreditation Board of Hospitals (NABH) or any other medical regulation body in India has recommended requirement for these particular directives.	Following the international health emergency COVID-19, deadline was postponed the by one year to 26 May 2021. Therefore, it is imperative that all companies of good repute should comply with European Union Medical Device Regulation 2017/745. Amendment to read as **''BIS/MDR European CE issued by a four digit notified body as per (EU) n.2017/745"** WEE – WEEE 2012/19/EU Waste Electrical and Electronic Equipment Directive & REACH 1907/2006/EU registration deleted in past Amendment.
4.	4. Washer Disinfector with Accessories (Pg. 8 of Technical Specifications) • Washer should be operated by a 7'' colour touch screen on both soiled & clean sides **Amendment Request:** 7" is manufacturer-specific to foreign OEM of *M/s.* Med Freshe Private Limited. A range should be given to bidders, say "4"-7"" for wider participation.	4. Washer Disinfector with Accessories (Pg. 8 of Technical Specifications) • Washer should be operated by a 4" – 7'' colour touch screen on both soiled & clean sides
5.	5. Low Temperature Plasma Sterilizer (Pg. 8) Operational volume 150 – 175 Liters **Amendment Request:** A wider range should be given to bidders and to be	5. Low Temperature Plasma Sterilizer (Pg. 8) **Tender terms and condition prevail**

	amended as: "Operational volume 100 – 175 Liters"	
6.	5. Low Temperature Plasma Sterilizer (Pg. 9) i) The unit should have facility to increase H202 contraction *(sic)* from 59 % to up to 90 % or above to increase the speed and efficacy of the sterilization process. **Amendment Request:** This is a very biased clause. No reputed manufacturer in USA, Europe or India will be able to comply with this. For efficient plasma sterilization, a concentration of "58-60%" is enough to achieve low temperature sterilization as per norms. Logically, please clarify how a plasma sterilizer can increase the concentration of H2O2 within the duration of a cycle when the H2O2 bottle/cassette has a fixed concentration of compound present in it? In addition, such high concentration (90%) of H2O2 cannot be sourced in India unless the company is involved in the manufacturing of paper. This clause must be omitted and plasma concentration of "58-60%" should be specified.	Tender terms and condition prevail.
7.	6. LOW TEMPERATURE STEAM FORMALDEHYDE: 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%. **Amendment Request:** This particular clause is specific to a single manufacturer, foreign OEM of Med Freshe Pvt. Ltd. No sane manufacturer in their right mind will supply LTSF sterilizers with more than 2% formaldehyde. Why is HSCC India Limited playing with lives of CSSD technicians in India by specifying 34-38% formalin and promoting cancer?	(EN 14180 + A2) (Page 13 of the technical specification) This European Standard specifies requirements and tests for LTSF sterilizers. These sterilizers are primarily used for the sterilization of heat labile medical devices in health care facilities. This European Standard specifies minimum requirements: a) for the performance and design of sterilizers to

	Did you know that formaldehyde has likely carcinogenic properties? In January 2016, the European Union (EU) officially adopted the reclassification of formaldehyde (CLP Regulations EC 1272/2008) as a Class 1B carcinogen (ie, a presumed human carcinogen) and Class 2 mutagen. Studies indicate that formaldehyde is a mutagen and a potential human carcinogen, and OSHA regulates formaldehyde. The permissible exposure limit for formaldehyde in work areas is 0.75 ppm measured as a 8-hour TWA. The OSHA standard includes a 2 ppm STEL (i.e., maximum exposure allowed during a 15-minute period). The formaldehyde standard requires that the employer conduct initial monitoring to identify employees who are exposed to formaldehyde at or above the action level or STEL. If this exposure level is maintained, employers may discontinue exposure monitoring until there is a change that could affect exposure levels or an employee reports formaldehyde-related signs and symptoms. The formaldehyde steam sterilization system has not been FDA cleared for use in healthcare facilities. This item should be deleted from BOQ.	ensure that the process is capable of sterilizing medical devices b) for the equipment and controls of these sterilizers necessary for the validation and routine control of the sterilization processes.

The bid submission date is extended from 04.01.2023 to 18.01.2023.

All other terms & conditions remain unchanged.

Sd/-
Director, LHMC, New Delhi