HSCC/SES/CSSD/AIIMS/Raebareli/2020 Date :19.10.2020

All Bidders

Amendment –IV

Project: Supply, Installation, Testing & Commissioning of CSSD for Hospital Block, All India Institute of Medical Sciences (AIIMS), Raebareli.

IFB No. HSCC/SES/CSSD/AIIMS/Raebareli/2020 Dated 15.09.2020

This has reference to above IFB. 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. 1 Horizontal Double Sliding Door Autoclav**e, as per the guidelines of ministry, you have clearly mentioned that the equipment should meet BIS/EN ISO/IEC Directives and the product should be BIS/US FDA/European CE. The manufacturer should have ISO 13485 and EN 285 or BIS. This is very well noted. However, in the **Item no.2 Sterilizer 250 litres**, it is mentioned - the product should meet EN ISO/IEC directives and product should be BIS/ISO/USFDA/European CE Certified with FOUR DIGIT NOTIFIED BODY NUMBER; whereas it should have been written as **European CE** mark because no manufacturer in India has CE with 4-digit notified body number.	**Item no. 1 Horizontal Double Sliding Door Autoclav**e: It should meet BIS/EN ISO / IEC directives and product should be US FDA/European CE certified with four digit notified body number. The manufacturer should have ISO 13485:2003 and EN 285 for Large Autoclaves (Europe) or USA: ST8 – Hospital Sterilizers. For the **Item no.2 Sterilizer 250 litres** It should meet BIS/EN ISO / IEC directives and product should be US FDA/European CE certified with four digit notified body number. The manufacturer should have ISO 13485:2003 and EN 285 for Large Autoclaves (Europe) or USA: ST8 – Hospital Sterilizers
2.	We found that notified body CE with 4-digit number is asked in the specs of Item no. **3 Rapid Sterilizer** and item no. **4. Double Door Washer Disinfector** also. No manufacturer in India has notified body CE with 4-digit no. and the specs should be amended by removing '*four digit notified body number'*. Moreover in Double door Washer Disinfector, European CE should only be asked for, as there is no BIS Standard for this equipment.	Should be BIS/ US FDA/European CE certified with four digit notified body number. Manufacturer should be ISO 13485:2003 , EN ISO15883 and ISO9001 certified and copy of the certificates
3.	In the Specifications of item no. **5 Plasma Sterilizer**	Should be BIS/ US FDA/

	Double Door, it is rightly mentioned as European CE Certified, but Item no. **6 Ultrasonic Cleaner** European CE with four digit notified body number is asked. It is very much surprising to find that European CE with four digit notified body number is asked in comparatively less sophisticated items. It should be written as CE marked/IS Standard, if available. Otherwise, it will only favour one or two bidders and the participation will be limited.	European CE certified with four digit notified body number.
4.	Rapid Steriliser (Flash Autoclave) Table Top Steriliser with Accessories for TSSU Capacity : Minimum 20L To be read as: Capacity : 18-30L	Capacity : 18-30L
5.	Types of Cycle Process Table Top Steriliser should be Sterilisers should be equipped with B process, N process as per latest EN 13060/S Class (Customised Cycle). Proof of declaration of conformity. To be read as: Type of Cycle Process : Table Top Sterilisers should be equipped with B Process OR N Process as per latest EN 13060 OR S-Class (Customised Cycle). Proof of declaration of conformity.	Type of Cycle Process : Table Top Sterilisers should be equipped with B Process OR N Process as per latest EN 13060 OR S-Class (Customised Cycle). Proof of declaration of conformity.
6.	Air Filter :Air filter should be provided for filtering the atmospheric air before entering inside the chamber. The filter separation efficiency should be higher than 99.998% for particle size less than 0.3 µm. Air filter should be covered warranty and CMC period. To be read as: Air filter: Air Filter should be provided for filtering the atmospheric air before entering inside the chamber. The Filter separation efficiency should be higher than 99.998% for particle size less than 0.3 µm OR equivalent. Air filter should be covered warranty and CMC period.	Air filter: Air Filter should be provided for filtering the atmospheric air before entering inside the chamber. The Filter separation efficiency should be higher than 99.998% for particle size less than 0.3 µm OR equivalent. Air filter should cover warranty and CMC period.
7.	Water Storage Tank: Steriliser should have inbuilt water reservoir with storage capacity upto 5L. The water reservoirs should have easy access for cleaning and to avoid bio film. To be read as: Water Storage Tank: Steriliser should have inbuilt water reservoir with storage capacity from 3 -8 L.	Water Storage Tank: Steriliser should have inbuilt water reservoir with storage capacity from 3 -8 L. The water reservoirs should have easy access for cleaning and to avoid bio film.

	The water reservoirs should have easy access for cleaning and to avoid bio film.	
8.	Steam Generator: Steriliser should have inbuilt steam generator. The steam generator design should be with integrated energy storing system for building up power for sterilisation loads in short time. To be read as: Steam Generator: Steriliser should have inbuilt steam generator OR Heating Jacket. The steam generator /Heating Jacket design should be with integrated energy storing system for building up power for sterilisation loads in short time.	Steam Generator: Steriliser should have inbuilt steam generator OR Heating Jacket. The steam generator /Heating Jacket design should be with integrated energy storing system for building up power for sterilisation loads in short time.
9.	Control Panel: The control system should be microprocessor based PLC system specially designed for sterilization applications. The control system should have CPU processor with battery backup, Digital input /output controls, analogue measuring inputs & COM ports for printer & PC connectivity. To be read as: Control Panel: The control system should be microprocessor based PLC system specially designed for sterilization applications. The control system should have CPU processor with battery backup, Digital input /output controls, analogue measuring inputs & COM ports for printer & PC connectivity. Or The control system should have SD card input, which can allow storage of data and be viewed on any PC/Laptop using SD card reader.	Control Panel: The control system should be microprocessor based PLC system specially designed for sterilization applications. The control system should have CPU processor with battery backup, Digital input /output controls, analogue measuring inputs & COM ports for printer & PC connectivity. Or The control system should have SD card input, which can allow storage of data and be viewed on any PC/Laptop using SD card reader.
10.	Plasma Steriliser (Double Door) / Low Temperature Steriliser 120-150L The steriliser process must have maximum material device manufacturers' recommendations from major endoscopic equipment manufacturers. To be read as: The steriliser process must have maximum material device manufacturers' recommendations from major endoscopic equipment manufacturers Or bidder should attach Cytotoxicity Test Report and Validation of H2O2 plasma steriliser according to ISO14937 not more than 5 years old.	The steriliser process must have maximum material device manufacturers' recommendations from major endoscopic equipment manufacturers Or bidder should attach Cytotoxicity Test Report and Validation of H2O2 plasma steriliser according to ISO14937 not more than 5 years old.
11.	Ultrasonic Cleaner (40L) Ultrasonic cleaner should be either ISO-13485	Ultrasonic cleaner manufacturer should be ISO - 13485 certified with

	certified with declaration of conformity as per BIS/US FDA/European CE certified with four digit notified body number. To be read as: Ultrasonic cleaner manufacturer should be ISO - 13485 certified with Declaration of conformity to BIS/US FDA/European CE. (Since it is not a medical device).	Declaration of conformity to BIS/US FDA/European CE.
12.	Heat Sealing Machine It should be BIS/European CE/US FDA certified. To be read as: It should have Declaration of Conformity to BIS/US FDA/European CE from manufacturers (Since it is not a Medical Device.)	It should have Declaration of Conformity to BIS/US FDA/European CE from manufacturers

The bid submission date is extended from 20.10.2020 to **29.10.2020** and bid security should be valid for 180 days from the date of original bid submission ie. from 30.09.2020.

All other terms & conditions remain unchanged.

Chief General Manager, HSCC (I) Ltd.
As Executing Agency of Ministry of Health & FamilyWelfare