Response To Pre-Bid Queries (Pre-Bid date: 21.12.2022)				
GeM Bid Number: GEM/2022/B/2860352 Dated: 16-12-2022				
Item Name: Flash Sterilizer				
Sr. No.	**Buyer Specification Document para and pg**	**Tender Specification**	**Representation received from Bidder**	**COMMITTEE RECOMMENDATION**
1	Para 6, page 1	Types of Cycles Process: Table Top Sterilizers should be equipped with B-process/N process/S Cycle as per latest EN 13060. Proof of declaration of conformity	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. Remarks: 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.	Types of Cycles Process: Table Top Sterilizers should be equipped with B-process as per latest International standards. Flash / Custom cycle / S-Class/ N Process as per the latest EN 13060. Proof of declaration of conformity.

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			EN ISO 13485: 2003 complies EN 13060. So. No need for separate and addition require of EN 13060 Reason: A). EN ISO 13485:2003 says that This International Standard specifies requirements for a quality management system that can be used by an organization for the design and development, production, installation and servicing of medical devices, and the design, development, and provision of related services. It can also be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer and regulatory requirements. B). EN 13060 - EN 13060 is the reference norm for ONLY small water steam sterilizers. Small steam sterilizers are used for materials and equipment which are likely to come into contact with blood or body fluids. This European Standard applies to small steam sterilizers used primarily for the sterilization of medical devices with a chamber volume of less than 60 liters ONLY. C). So, EN ISO 13485: 2003 is only for the table Top / Flash Sterilizer.	
2	Para 5, page 1	Quality Standards: Sterilizer should be US FDA/European CE certified with four digit notified body number/ BIS Approved	There Has no BIS Standard for Flash Sterilizer (Front Load Type). So, Cancel the US FDA & European CE. Reason: A). There has an BIS standard for following for Hospital / Pharma Sterilizer: IS 3829 Part 1 , 3829 Part 2 , 3829 part 3 (So, 3829 part 3 complies for table top Sterilizer which means Vertical Cooker type Autoclave). B). US FDA / European CE Certificate is against the MII policy.	No change considered
3	Para 8, page 1	Door Design: Should have radially opening door with at least one or two locking bolts for enhanced door safety. The doors should come with silicon elastomeric rubber gasket to withstand temperature upto 140°C & 20-30 psi.	Door Design: Should have a radially opening / hinged door with at least one or two locking bolts for enhanced door safety. The doors should come with a silicon elastomeric rubber gasket to withstand temperatures up to 140°C & 20- 30 psi. Remarks: We request you to kindly allow the both types of Chamber door as it does not make any effect on sterilization process.	Door Design: Should have radially opening/hinged door with at least one or two locking bolts for enhanced door safety. The doors should come with silicon elastomeric rubber gasket to withstand temperature upto 140°C & 20-30 psi.

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4	Para 11, page 1	Water Storage Tank: Sterilizer should have inbuilt water reservoir with storage capacity up to 3.5 to 5 L. The water reservoirs should have easy access for cleaning & to avoid bio film.	**OBSERVATIONS:** Now a days high end autoclaves come with Dual water reservoirs, one for fresh water and another for used water to avoid manual cleaning of the water reservoir. In that case Dual water reservoirs are offering more storage capacity. The manual cleaning needs interruption in working also as the unit would be off for some time. Sometimes it has been noticed that color & lint of the wrapped (linen) load is mixed with water which is not recommended to be recirculated. **REQUEST:** Either the specifications should be revised or both types of autoclaves, offering single water reservoir and Dual water reservoirs should be accepted.	No change considered
5	Para 13, page 1	Alarms: Automatic process checking & failure correction should be possible by the control system. The range of alarm should include Temperature & pressure sensor failure, phase timeout, 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 audiovisual.	**OBSERVATIONS:** "Power failure (less than 10 sec should be ignored)"; is practically impossible in case of Sterilizer. Sterilizer is a very complicated and service oriented equipment comprising of electrical, Electronic & mechanical engineering. It has electronic board, transformer, solenoid valves, heating chamber, and vacuum pump dealing with high temperature, pressure, steam & vacuum. In case of power failure, cycle may be at water sucking phase (from water reservoir to chamber), stem generation phase, heating phase, pre or post vacuum phase, condensation or drying phase. Electrical & Mechanical components/devices don't respond like electronic components/devices and cannot be controlled like that also. It can be achieved only by connecting the unit with uninterrupted & stabilized power supply. **REQUEST**: The phrase "Power failure (less than 10 sec should be ignored)" should be deleted.	Alarms: Automatic process checking & failure correction should be possible by the control system. The range of alarm should include Temperature & pressure sensor failure, phase timeout, doors not properly closed, power failure, continuous self-checking of all the safety devices, low water level etc. All the alarms should be audiovisual.

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6	Para 14, page 1	Accessories: The sterilizer unit should include rack with 3 or more levels & suitable size instrument trays should be the part of the supply for every sterilizer. The Sterilizer should have water circulation system so that no drain point & fixed water inlets required	Accessories: The sterilizer unit should include a rack with 3 or more levels & suitable size instrument trays should be part of the supply for every sterilizer. The Sterilizer should have a water circulation system so that no drain point & fixed water inlets are required. Also Stainless Steel Table, Water distiller should be supplied along with equipment. Remarks: The requested item may also please be incorporated to enable the smooth operation of the machine.	No change considered
			OBSERVATIONS: "The Sterilizer should have water circulation system so that no drain point & fixed water inlets required" Firstly the used water cannot be circulated for indefinite period and it has to be drain out after completion of few cycle through a drain knob. Sometimes it has been noticed that color & lint of the wrapped (linen) load is mixed with water which is not recommended to be recirculated. Secondly as explained above against point 11, now a days high end autoclaves come with Dual water reservoirs, one for fresh water and another for used water. A sterilizer with Dual water reservoirs doesn't do recirculation of water and the used water is drained out automatically. **REQUEST:** the specifications should be amended as "The Sterilizer should have water circulation (from water reservoir to chamber & chamber to water reservoir) and draining system so that no plumbing work concerning extra drain point & fixed water inlets are required; whether single water reservoir or Dual water reservoirs system."	