16-01-2023

Amendment no. 3

Sub: Technical Specification Amendment for the tender of Mother & Child Block -AIIMS , New Delhi-110029.

Ref.: GeM Bid No GEM/2022/B/2704805 Dated: 05-11-2022 for item ':Low temperature hydrogen peroxide plasma sterilizer (50L) (Qty: 02 nos.)'

The following changes are being incorporated in the above referred GeM Bid Number only.

Sr. No.	Buyer Specification Document para and pg	Existing Tender Specification	Read As
1	Para 3, pg 1	Sterilizer should use hydrogen peroxide gas plasma technology inside the chamber using RF energy for better efficacy and avoid the residual hydrogen peroxide for the safety of user and instruments.	Sterilizer should use hydrogen peroxide gas plasma technology inside the chamber using RF energy **/High Voltage Technology/ any other plasma generation method** for better efficacy and avoid the residual hydrogen peroxide for the safety of user and instruments.
2	Para 5, pg 1	The total capacity of sterilizer should be in between 25 to 50 liters	The total usable capacity of sterilizer should be in between 25 to 50 liters
3	Para 6, pg 1	Fastest cycle time should be less than 30 minutes with automated moisture check cycle before the start of the cycle to reduce cycle cancellation and wastage of sterilant and time.	Fastest cycle time should be less than 30±5 minutes and longest cycle should not be more than 60±5 minutes, with automated moisture check cycle before the start of the cycle to reduce cycle cancellation and wastage of sterilant and time.
4	Para 7, pg 1	Should have in built facility to completely monitor the operations with audio visual alarm and biological indicator with 15 min readout time.	Should have in built facility to completely monitor the operations with audio visual alarm and biological indicator with 15-30 min readout time.
5	Para 8, pg 1	BIS/USFDA certificate /CE certificate for sterilization of metal and non-metal instruments, stainless steel lumens	Manufacturer should have ISO 13485 certification issued from : Any Certification Bodies registered with NABCB under Medical Devices Quality Management System

			OR Any notified body registered with CDSCO OR Any 4-digit CE notified body
6	Para 11, pg 1	The sterilizer should have continuous H2O2 monitoring using UV sensor within the chamber to ensure that sterilant concentration always remains within industry specified OSHA limit of <1ppm.	The sterilizer should have continuous H2O2 monitoring using suitable sensor within the chamber to ensure that sterilant concentration always remains within industry specified OSHA limit of <1ppm.
7	Para 14, pg 1	Sterilizer should be environment friendly and should not leave any toxic or harmful residues. Sterilizer should be approved by Environmental Protection Agency (EPA) and EPA document to be submitted by bidder.	Sterilizer should be environment friendly and should not leave any toxic or harmful residues. Sterilizer should be approved by Environmental Protection Agency (EPA) and EPA document to be submitted by bidder or any equivalent safety documents
8	Para 22, pg 1	Sterilant should be in cassettes /cartridge form with individual ampule for accurate and calibrated dispensing of the sterilant. Sterilant can be stored at room temperature with leak proof indicator.	Sterilant should be in Bottle/ cassettes /cartridge form with leak proof indicator should be safe for handling & transportation and can be stored at room temperature.
9	Para 24, pg 1	Sterilization claim should be validated using approved biological indicators with 15 minutes reading time. Sterilizer, BI Reader with printer and BI indicator should be from same manufacturer for the accuracy of result.	Sterilization claim should be validated using approved biological indicators with 15-30 minutes reading time. Sterilizer, BI Reader with printer and BI indicator should be from same manufacturer for the accuracy of result.
10	NA	Added Para:	Should be supplied with Tyvek role of 5 different sizes- 5 roll each size Sealing machine, UPS with 1hr backup, Printer paper-60 Nos
11	NA	Added Para:	Each Machine should be supplied with following Instrument Tray with mat 1. Instrument Tray -24" X 8" X 2" (610 x 203 x 51)mm 2. Instrument Tray 24" X 13" X 4" (610 x 330 x 102)mm 3. Tray Mat-17" x 7.5" (432 x 191)mm fits tray 13830
12	NA	Added Para:	BOQ
			1. Plasma Sterilizer as per specification- 1 No

			2. Sealing Machine - 1 No
			3. Tyvek role of 5 different sizes- 5 roll each size
			4. UPS- 1 No
			5. Printer Paper- 60 Nos
			6. Instrument Tray 24" X 8" X 2" (610 x 203 x 51)mm- 01 No
			7. Instrument Tray 24" X 13" X 4" (610 x 330 x 102)mm- 01 No
			8. Tray Mat-17" x 7.5" (432 x 191)mm fits tray 13830- 01 No
13	NA	Added Para:	Price of essential consumables as shown below to be quoted separately which shall be considered for bid ranking(the unit price should be fixed for 10 years). These consumables may be ordered as and when required by the user department

			Item Description	**Quantity (approx. qty over 10 years being factored for bid ranking purposes only)**
			1. Strerilant	6000 cycles
			2. Biological Indicator	500
			3. Chemical indicator strip	30000

			4. SELF SEAL POUCH With Chemical Indicator 75 X 200 MM	6000 Pouches
			5. SELF SEAL POUCH With Chemical Indicator 150 X 320 MM	6000 Pouches
			6. SELF SEAL POUCH With Chemical Indicator Indicator200 X 400 MM	12000 Pouches
			7. Roll 150 MM X 70 M	120
			8. Roll 250 MM X 70 M	120
			9. Chemical Indicator Tape	500
			10. Thermal printer paper	60 rolls

Important Note:

1. Prospective Bidders are advised to check the GeM Portal regularly prior to the closing date and time of online submission of bid.

2. The Bid Security/EMD shall be valid for 110 days from Techno – Commercial Tender opening date. The techno-commercial tender opening date shall be considered as mentioned in bid document read with it's amendment(s), if any.

3. In reference to the extension of bid opening date as mention on GeM portal, Participating bidders, who are submitting their Bid security/EMD in the form of Bank Guarantee (BG) or FDR are instructed to extend the validity of their BG/FDR accordingly, i.e. required validity of EMD is to be kept in line with the extended bid opening date.

4. Traders/resellers/distributors/authorized agents will not be considered for availing benefits under PP Policy 2012 for MSEs as per MSE guidelines issued by MoMSME

5. Bidders shall ensure that their tender(s), complete in all respects, are submitted online through **GeM portal only**.