20-05-2022

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/2084554 Dated: 02-04-2022 for item 'Electrosurgical Unit high end with Argon Plasma and vessel sealing (Qty: 04 nos.)'

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

Sr. No.	Buyer Specification Document Page & Para	EXISTING TENDER SPECIFICATION	Read As
1	Pg 1 Para 23 (b)	Manufacturer should have valid ISO 13485 certification for quality standards.	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
2	Pg 2 Para 9	**Following accessories to be supplied with the Unit All from Same OEM only:** All the mentioned above Units & Accessories should be from Same OEM & Should have Valid USFDA/ European CE Certifications Marked.	Following accessories to be supplied with **each Unit :** All the mentioned above Units & Accessories should be from Same OEM.
3	Pg1 Para (Argon Plasma Coagulation (APC Unit))	NA	**Added Para:-** APC should be European CE with four digit notified body number or US FDA or BIS approved for the quoted model and certificate to be submitted. **OR** should meet IEC 60601-1, IEC 60601-1-2 & IEC 60601-2-2 standards and should submit valid test report for the quoted model from NABL accredited laboratory/ from labs in their country of origin in case of foreign manufacturer.
5	Pg 1 Para 3	Unit should have a Step guide suggesting appropriate setting configurations for every instrument and application	Unit should have a **Step guide / equivalent** setting configurations for every instrument and application

Sr. No.	Buyer Specification Document Page & Para	EXISTING TENDER SPECIFICATION	Read As
10	Pg 1 Para 20	The generator should be compatible with Hydrojet technology to facilitate use of unique hybrid technology instruments for Soft Tissue &Liver Dissections from the same OEM if required in future by the user Deptt	**Deleted**
11	Pg 1 Para 22	Unit should support Nessy as a neutral electrode safety feature for the patients benefits	Unit should support patient Return safety feature for the patients benefits Electrode Monitoring
12	Pg 2 Para (APC unit), point 7	Should have the facility to use unique hybrid instruments for conditions like Barrett's Exophages	**Deleted**

All other contents of the Bid Document including terms & conditions remain unaltered.

Note: Prospective Bidders are also advised to check the GeM Portal regularly prior to the closing date and time of online submission of bid