

Response To Pre-Bid Queries (Pre-Bid date: 22.02.2022)

Bid Number: GEM/2022/B/1943446 Dated: 10-02-2022

Item Name: Vacuum Assisted Delivery System

Sr. No.	Buyer Specification Document Page & Para	TENDER SPECIFICATION	REPRESENTATION RECEIVED FROM THE FIRM	COMMITTEE RECOMMENDATION
1	Pg 1 Para 5	It should have autoclavable double jars (2.5ltr.) of unbreakable PSU material with disposable collection system with highly burst resistant and double layers liners.	Request you to amend with option of the material of 2.5 Ltr Jars with unbreakable PC (Poly Carbonate)/unbreakable PSU Material. 2.5 Ltr unbreakable Polycarbonate Jar Clinical Relevance: It ensures complete protection against nosocomial / hospital acquired infections amid the ongoing pandemic both for healthcare worker and surgeon.	Amended as: It should have autoclavable double jars (2.5ltr.) of unbreakable PC (Poly Carbonate)/ unbreakable PSU material with disposable collection system with highly burst resistant and double layers liners.
2	Pg 1 Para 17	It should be USFDA approved.	Request you to please add USFDA & CE Approved as to maintain the quality of the product.	Amended as: Equipment Should be European CE with four digit notified body number or USFDA or BIS approved for the quoted model and certificate to be submitted.
3	Pg 1 Para 18	It should also have certification of ISO 9001, ISO 13485, CE 0123	We don't have ISO 9001 where as our product is certified with ISO 13485 & CE0123 which are required for maintaining the medical grade product. Requesting you to please remove the requirement of ISO 9001. ISO 13485, CE 0123 Clinical Relevance: International quality certifications for better product quality	Amended as: Manufacturer should have ISO 13485 certification.