

Response To Pre-Bid Queries (Pre-Bid date: 17.08.2022)				
Bid Number: GEM/2022/B/2393775 Dated: 29-07-2022				
Item Name: Vulval and Vaginal Surgery set				
Sr. No.	Buyer Specification Document Page & Para	TENDER SPECIFICATION	REPRESENTATION RECEIVED FROM THE FIRM	Reply to prebid queries
1	Pg 2 Para 44	The Instruments should be US-FDA or European CE approved	The instruments should be CE or BIS certified or ISO 13485 certified	Added Para:-Manufacturer should have ISO 13485 certification
2	NA	Suggested by Bidder	Should be US FDA / European CE (From 4 Digit Notified Bodies under Directive: 93/42/EEC Medical devices). Reasoning: For assurance of Instrument quality as per international standard.	
3	Pg 1 Para 44	All instruments should be US FDA or European CE approved	The Instrument should be USFDA or European CE certified and ISO.	
4	NA	Suggested by Bidder	Bidder should quote for all the instruments of the set . Atleast 75% of the quoted instruments should be from same manufacturer and from another manufacturer 25%	no change considered