

Response To Pre-Bid Queries (Pre-Bid date: 17.08.2022)				
Bid Number: GEM/2022/B/2395789 Dated: 29-07-2022				
Item Name: Gynae Instrument Set				
Sr. No.	Buyer Specification Document Page & Para	TENDER SPECIFICATION	REPRESENTATION RECEIVED FROM THE FIRM	Reply to prebid queries
1	Pg 1 Para 2	The Instruments should be US-FDA or European CE certified.	<p>The instruments should be CE or BIS certified or ISO 13485 certified</p> <p>Should be US FDA / European CE (From 4 Digit Notified Bodies under Directive: 93/42/EEC Medical devices).</p> <p>Reasoning: For assurance of Instrument quality as per international standard.</p> <p>The Instrument should be USFDA or European CE certified and ISO.</p>	Added Para:-Manufacturer should have ISO 13485 certification
2	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