

Response To Pre-Bid Queries (Pre-Bid date: 17.08.2022)				
Bid Number: GEM/2022/B/2395202 Dated: 29-07-2022				
Item Name: Microlaryngeal Surgery Set				
Sr. No.	Buyer Specification document Page & Para	TENDER SPECIFICATION	REPRESENTATION RECEIVED FROM THE FIRM	Reply to Pre-bid Queries
1	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.	may be amended as:- Manufacturer should have ISO 13485 certification
2	NA	Suggested by Bidder	Incorporation of safety certification i.e. USFDA or EUROPEAN CE by 4 Digit Notified Body	may be amended as:- Manufacturer should have ISO 13485 certification
3	NA	Suggested by Bidder	Permissible variations in size length of instruments.	May be Amended as:-10% variation in sizes is acceptable
4	NA	Suggested by Bidder	Please allow us to quote 90% instruments from the same manufacturer. For	Added Para:-Bidder should quote for all the instruments of the set . Atleast 75% of the quoted instruments should be from same manufacturer and 25% can be from different manufacturer
5	NA	Suggested by Bidder	The Instrument should be USFDA or European CE certified and ISO.	may be amended as:- Manufacturer should have ISO 13485 certification
6	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%	Added Para:-Bidder should quote for all the instruments of the set . Atleast 75% of the quoted instruments should be from same manufacturer and 25% can be from different manufacturer

Commercial Query				
Sr. No.	Buyer Specification document Page & Para	TENDER SPECIFICATION	REPRESENTATION RECEIVED FROM THE FIRM	Reply to Pre-bid Queries
1	NA	Suggested by Bidder	Kindly make amendment in the MII clause which will enable us to quote quality products as per the tender requirements which are not made in India.	No change considered
2	NA	Suggested by Bidder	Allow us to quote substitute products irrespective of the item/name referring to a particular manufacturer/proprietor where the functionality and quality of the outcomes will not be compromised while keeping fare competition	No change considered