

| Response To Pre-Bid Queries (Pre-Bid date: 17.08.2022) |  |  |  |  |
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| Bid Number: GEM/2022/B/2397511 Dated: 30-07-2022       |  |  |  |  |
| Item Name: Abdominal instruments set                   |  |  |  |  |
| Sr. No.  | Buyer Specification Document Page & Para | TENDER SPECIFICATION                                       | REPRESENTATION RECEIVED FROM THE FIRM  | Reply to Pre-bid Queries   |
| 1  | Pg 1<br>Para 2                           | The Instruments should be US-FDA or European CE certified. | The instruments should be CE or BIS certified or ISO 13485 certified<br>The Instrument should be USFDA or European CE certified and ISO.   | Added Para:- Instrument should be USFDA or European CE or BIS or ISO 13485 certified   |
| 2  | NA                                       | Suggested by Bidder  | Should be US FDA / European CE (From 4 Digit Notified Bodies under Directive: 93/42/EEC Medical devices).<br>Reasoning: For assurance of Instrument quality as per international standard. |  |
| 3  | 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 from another manufacturer 25% |