

**Response To Pre-Bid Queries (Pre-Bid date: 21.12.2022)**

**GeM Bid Number: GEM/2022/B/2860847 Dated: 16-12-2022**

**Item Name: Pediatric Urology surgical trainer/Simulator**

Sr. No.	Buyer Specification Document para and pg	Tender Specification	Representation received from Bidder	COMMITTEE RECOMMENDATION
1	Para 14 (Certification), pg 6	System should have European CE with 4 digit notified body/ USFDA/ BIS certified and certificate to be submitted.	Should be deleted or amended to be read as : Should have US FDA /European CE / ISO9001:2015 certification /Declaration of Conformity of manufacturer or BIS certification. Remarks: Pediatric Urology surgicaltrainer/Simulator is a trainingmodule for PG students /Residents / Faculties in acomputerized environmentand not on actual patient in Operation theatre and hence do not require US FDA or CEcertification or BIS approval.Though for standarquipment for Medical research it requires ISO Certification. We areexclusive distributor of M/sVirtamed Switzerland inIndia, who are world famous for manufacturing thisproduct and they have ISO 9001:2015 Certification.	Should have US FDA /European CE / ISO9001:2015 certification /Declaration of Conformity of manufacturer or BIS certification.