MINUTES OF GRIEVANCE COMMITTEE MEETING FAISALABAD INSTITUTE OF CARDIOLOGY, FAISALABAD

A meeting of Grievance Committee for product of Cardiac Surgical Disposable Items for F.Y. 2021-22 was held on 25.11.2021 at 10:00 AM in the Office of the Medical Superintendent, Faisalabad Institute of Cardiology, Faisalabad.

CARDIAC SURGICAL DISPOSABLE

1. M/s Vertex Medical (Pvt.) Ltd.

Item #	Item Name	Brand Name	Manufactured By / Imported By	TAC Observations	GC Observation	Remarks
1	OXYGENATOR- MEMBRANE WITH LOW PRIMING VOLUME	Lilliput- D902	LivaNova (Sorin) Italy	1. EC certificate of D-902 (Peads) Oxygenator not attached	1. EC certificate of D-902 (Peads) Oxygenator attached	Accepted
	FDA/CE APPROVED, WITH CUSTOM PACK FOR PEADS			2. Free Sale Certificate embassy attested not attached	2. Free Sale Certificate embassy attested attached	

M/s Vertex Medical (Pvt.) Ltd.

Sr.	Description	Firm Grievance	GC Observation	Decision
1	Grievance Against M/S Cardiac Care	 The firm claims that the oxygenator quoted by M/S Cardiac Care Trilly euorset Italy is not FDA approved Oxygenator Trilly euorset Italy has following drawbacks a. Priming volume is very high 99 ml b. Its heat exchanger surface area is very high 0.04 m² c. very high blood foreign surface contact area 0.84 m² 	 FDA is not compulsory parameter as the firm have CE certification according to specifications of technical End user satisfied by the product 	Grievance rejected

Mrs. Iqra Munir, Pharmacist, FIC, Faisalabad.

Engr. Sharaz Ali Bio Medical Engineer FIC, Faisalabad. Dr. Rehan Riaz Assistant Prof. of Cardiac Surgery, FIC, Faisalabad.

Dr. Shahbaz Ahmad Khiliji, Associate Prof. of Cardiac Surgery, FIC, Faisalabad. Zafar Abbas Khan, Medical Superintendent, FIC, Faisalabad.