

**MINUTES OF GRIEVANCE COMMITTEE MEETING
FAISALABAD INSTITUTE OF CARDIOLOGY, FAISALABAD**

A meeting of Grievance Committee for product of Cardiac Surgical Disposables (Re-Tender) F.Y.2023-24 was held on 23-01-2024 at 11.00 am in the Office of the Medical Superintendent, Faisalabad Institute of Cardiology, Faisalabad.

Cardiac Surgical Disposables

M/s Friends Enterprises

Item #	Item Name	Brand Name	Manufactured by	TAC Observations	GC Observation	Remarks
3	Central Venous Catheterization Set Quad Lumen 8FR/8.5FR	8.0 FR Arrow	Teleflex USA	<ul style="list-style-type: none"> Sufficient Punjab teaching Govt. institute experience not attached Sample not provided 	<ul style="list-style-type: none"> Insufficient Punjab teaching Govt. institute experience attached Sample not provided 	Rejected

M/s Flowtrnoix System

Item #	Item Name	Brand Name	Manufactured by	TAC Observations	GC Observation	Remarks
3	Central Venous Catheterization Set Quad Lumen 8FR/8.5FR	Able/ Guangdong BAIHE Medical	Able/ Guangdong	<ul style="list-style-type: none"> Punjab teaching Govt. institute experience not attached 	<ul style="list-style-type: none"> Insufficient Punjab teaching Govt. institute experience attached 	Rejected
15	Epicardial Bipolar Lead	Biotronik	Biotronik Germany	<ul style="list-style-type: none"> Sufficient Punjab teaching Govt. institute experience not attached 	<ul style="list-style-type: none"> Insufficient Punjab teaching Govt. institute experience attached 	Rejected
16	Epicardial Lead Unipolar	Biotronik	Biotronik Germany	<ul style="list-style-type: none"> Sufficient Punjab teaching Govt. institute experience not attached 	<ul style="list-style-type: none"> Insufficient Punjab teaching Govt. institute experience attached 	Rejected
43	Sucker Nozzle Adult	Andocor	Andocor Belgium	<ul style="list-style-type: none"> Invalid FSC Attached 	<ul style="list-style-type: none"> Valid FSC Attached 	Accepted
44	Sucker Nozzle Paeds.	Andocor	Andocor Belgium	<ul style="list-style-type: none"> Invalid FSC Attached 	<ul style="list-style-type: none"> Valid FSC Attached 	Accepted
46	Surgical Spring Clip (Bulldog)	Changzhou Kangxin Medical	Changzhou Kangxin Medical	<ul style="list-style-type: none"> EC Certificate not attached 	<ul style="list-style-type: none"> EC Certificate attached 	Accepted
52	Vessel Tip	Andocor	Andocor Belgium	<ul style="list-style-type: none"> Invalid FSC Attached 	<ul style="list-style-type: none"> Valid FSC Attached 	Accepted

M/S Cardiac care

Item #	Item Name	Brand Name	Manufactured by	TAC Observations	GC Observation	Remarks
10	DACRON VASCULAR TUBE GRAFT PRE COLLAGENIZED SIZE 22, 24, 26, 28, 30 FDA APPROVED CE	GETTINGE	GETTINGE, USA	<ul style="list-style-type: none"> Medical device registration not attached Name of manufacturer on EC certificate M/S Atrium Medical Corporation, USA while on technical offer gettinge, USA mentioned Name of manufacturer on free sale certificate M/S inter Vascular SAS, France while on technical offer gettinge, USA mentioned 	Medical device registration not attached	Rejected
35	PTFE GRAFT ALL SIZES (4,5,6 18,20,22)	GETTINGE	GETTINGE, USA	<ul style="list-style-type: none"> Name of manufacturer on EC certificate M/S Atrium Medical Corporation, USA while on technical offer gettinge, USA mentioned Name of manufacturer on free sale certificate M/S inter Vascular SAS, France while on technical offer gettinge, USA mentioned 	The firm provided relevant documents	Accepted
46	SURGICAL SPRING (BULL DOG)	PETER SURGICAL	PETER SURGICAL	Invalid EC attached	Valid EC attached	Accepted

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M/S Friends Enterprises

Sr.	Description	Firm Grievance	GC Observation	Decision
1	Grievance against M/s Mediland Pakistan	<p>The firm claims that item no. 23, 24 (IABP 40&34CC) quoted by M/s Mediland Pakistan is not registered in MDR.</p> <ul style="list-style-type: none"> M/s Mediland Pakistan never have valid FSC & EC Certificate. All documents are without Embassy Attestation. The firm didn't provide the sample 	The firm provided relevant documents	Grievance of M/S Friends Enterprises rejected and item no. 23, 24 (Intra aortic balloon 40CC & 34CC) accepted
2	Grievance against M/s Cardiac care	<p>The firm claims that item no. 23, 24 (IAB 40&34CC) of M/s Cardiac care quoted brand</p> <ul style="list-style-type: none"> Inshitra USA is already rejected in PPRA due to bankruptcy and not registered under Medical devices rules PPRA clearly mentioned in their decision that provided agreement with M/S Tennessee Medical seems dubious and M/S TNMI INC cannot be considered eligible unless it has been re-registered with DRAP 	<p>The DRAP issued a show cause notice vide letter No. F.12-5/2014-MD dated 02-03-2023 to M/S Cardiac care. The M/S Cardiac care provided the letter Ref/CC/TNMI/2023 on dated 04-04-2023 issued to DRAP in response of show cause notice.</p> <p>The said letter did not mention request to change the name of manufacturer. The letter did not fulfill the requirements and no response of DRAP received after 10 months.</p>	Grievance of M/s Friends Enterprises Accepted and the item no. 23, 24 (Intra aortic balloon 40CC & 34CC) of M/s Cardiac care rejected


M/s Mediland Pakistan (pvt) Ltd.

Sr.	Description	Firm Grievance	GC Observation	Decision
1	Grievance Against M/s Cardiac care and M/S Friends Enterprise	<p>The firm claims that item no. 23, 24 (IAB 40&34CC) of</p> <p>1.M/S Cardiac care and as per rule 1792) M/S Friends Enterprises quoted brands Inshitra USA and Arrow IABP catheter have compatibility issues with installed Maquet CS-300 & cardio saves hybrid intra-aortic balloon pump</p> <p>2. We have received a FDA recall regarding shut</p>	As per end user, there is no compatibility issue of intra aortic balloon pump/console with available brands of intra aortic balloon. End user satisfied	Grievance of M/S Mediland Pakistan Rejected


		<p>down of equipment due to blood entering into IABP</p> <p>3. Pump shut down may cause hemodynamic instability, organ damage and death of patient</p> <p>4. Release of helium gas bubbles into the blood, damage organs and brain and if pump shut down doesn't occur and therapy continues. Patient exposure to cross contaminant might be fatal and life threatening</p>		
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Mrs. Iqra Munir,
Pharmacist,
FIC, Faisalabad.
(Copt. Member)




Engr. Sharaz Ali
Bio Medical Engineer
FIC, Faisalabad.
(Member)




Mrs. Anila Saeed
Deputy Drug Controller,
FIC, Faisalabad.
(Member)



Dr. Rehan Riaz
Assistant Prof. of Cardiology,
FIC, Faisalabad
(Member)



Dr. Shahbaz Ahmad Khiliji,
Prof. of Cardiac Surgery,
FIC, Faisalabad
(Member)



Dr. Muhammad Nadeem Akhtar
Medical Superintendent,
FIC, Faisalabad
(Member)