

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

A meeting of Grievance Committee for product of Angiography & Angioplasty & Cardiac Surgical disposable items F.Y.2024-25 Re-tender II was held on 08-01-2025 at 11.00 am in the Office of the Medical Superintendent, Faisalabad Institute of Cardiology, Faisalabad.

Cardiac Surgical disposable

**1. M/s Safeway Systems Pakistan
Bid**

Sr. No.	Company Name	TAC Observations	GC Observation	Remarks
1	Bid Reject of M/s Safeway Systems Pakistan	1. Unhidden copy of bid security not attached 2. Invalid DSL attached 3. FBR/Income tax return/sales tax return for last three financial years not attached. 4. Bid form sign and stamped not attached	Relevant documents provided	Accepted

Item #	Item Name	Brand Name	Manufactured by	TAC Observations	GC Observation	Remarks/ Decision
54	Aortic cannula with connector straight (Adult) all sizes approved by FDA/CE	Cardiomed Canada	Nipro Cananda	1. Quality certification of CE not attached 2. Experience of public sector institute not attached 3. Invalid sole agency agreement attached 4. Invalid ISO 13485 attached	Relevant documents provided	Accepted
65	Venous cannula single satge all sizes (wire reinforced, straight) adult approved by FDA/CE	Cardiomed Canada	Nipro Cananda	1. Medical device registration not attached 2. Quality certification of CE not attached 3. Sufficient experience of public sector institute not attached 4. Invalid sole agency agreement attached 5. Invalid ISO 13485 attached	Relevant documents provided	Accepted

66	Venous cannula single stage all sizes (wire reinforced, straight) pears approved by FDA/CE (18,20, 22, 24, 26 FR)	Cardiomed Canada	Nipro Canada	<ol style="list-style-type: none"> 1. Quality certification of CE not attached 2. Sufficient experience of public sector institute not attached 3. Invalid Sole agency agreement attached 4. Invalid ISO 13485 attached 	Relevant documents provided	Accepted
75	Venous cannula two stage 36x50 FR approved by FDA/CE	Cardiomed Canada	Nipro Canada	<ol style="list-style-type: none"> 1. Medical device registration not attached 2. Quality certification of CE not attached 3. Free sale certificate not attached 4. Experience of public sector institute not attached 5. Invalid Sole agency agreement attached 6. ISO 13485 not attached 	Relevant documents provided	Accepted

Items with serial no. 03, 60, 61, 62, 63 and 64 in technical are approved of M/S Safeway systems, but financial opening is kept pending due to central purchase.

M/s Anax Associates (Pvt) Ltd

Sr.	Description	Firm Grievance	GC Observation	Remarks/ Decision
1	Grievance Against M/s Tech zone	<p>The firm claims that item no. 42 chlorhexidine gluconate 2% w/v dressing 8.5 cm x 11.5 cm is</p> <ul style="list-style-type: none"> • Not DRAP registered in class D medical device, as CHG dressing, which is a drug and has antimicrobial property must be classified as class D product • It has been registered in Class A 	<ul style="list-style-type: none"> • As per bidding documents valid DRAP registration is mandatory. Item no. 42 chlorhexidine gluconate 2% w/v dressing 8.5 cm x 11.5 cm of M/S Techzone (Brand: Yahfo, China) is DRAP registered. • Relevant documents 	Item no. 42 chlorhexidine gluconate 2% w/v dressing 8.5 cm x 11.5 cm of M/S Techzone accepted The grievance of M/S Anax Associates rejected. Furthermore,

		<p>medical devices under the category of catheter fixation dressing</p> <ul style="list-style-type: none"> M/S Tech zone was rejected by Holy Family Hospital, Rawalpindi in technical evaluation due to insufficient experience. 	provided	a clarification letter regarding DRAP registration in Class A, B, C, D has been sent to DRAP. Therefore,
		<p>The firm claims that item no. 51 Surgical Drape/ Incise Drape</p> <ul style="list-style-type: none"> Has been rejected by TEC due to not user friendly but accepted in GC on 07-12-2024. It has been registered as class A product but they donot have DRAP registration of antimicrobial drape that is in class D. M/S Techzone donot have sufficient Punjab teaching experience of 2 years as they were rejected by TEC and GC committees in annual tender of F.Y 24025 M/S Techzone donot have experience of one year as it is registered in June 2024 M/S Tech zone was rejected by Holy Family Hospital, Rawalpindi in technical evaluation due to insufficient experience. 	<ul style="list-style-type: none"> As PPRA Order No. L&M (PPRA) 540/2024/com dated. 15.10.2024, the GC accepted the product As per bidding documents valid DRAP registration is mandatory. Item no. 42 chlorhexidine gluconate 2% w/v dressing 8.5 cm x 11.5 cm of M/S Techzone (Brand: Yahfo, China) is DRAP registered. Relevant documents provided As per bidding documents one year market experience is not mandatory for medical devices. 	<p>Item no. 51 Surgical Drape/ Incise Drape of M/S Techzone accepted The grievance of M/S Anax Associates rejected. Furthermore, A clarification letter regarding DRAP registration in Class A, B, C, D has been sent to DRAP.</p>
	Grievance Against M/S Saru International	<p>The firm claims that item no. 51 Surgical Drape/ Incise Drape</p> <ul style="list-style-type: none"> Has been rejected by TEC due to not user friendly but accepted in GC on 07-12-2024. It has been registered as class B product but they donot have DRAP registration of antimicrobial drape that is in class D. Against M/S Saru International 	<ul style="list-style-type: none"> As PPRA Order No. L&M (PPRA) 540/2024/com dated. 15.10.2024, the GC accepted the product. As per bidding documents valid DRAP registration is mandatory. Item no. 51 Surgical Drape/ Incise Drape of M/S Techzone (Brand: Yahfo, China) is 	<p>M/S Saru International was already non-responsive in bid evaluation. Thus, the grievance of M/S Anax Associates rejected. Furthermore, A clarification letter regarding DRAP registration in Class A,</p>

		donot have Punjab Teaching experience of 2 years in said item.	DRAP registered. • Relevant documents provided	B, C, D has been sent to DRAP.
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M/s Anax Associates (Pvt) Ltd

Sr.	Description	Firm Grievance	GC Observation	Remarks/ Decision
1	Grievance Against M/s Tech zone	<p>The firm claims that item no. 60 Tape for skin hypoallergic adhesive</p> <ul style="list-style-type: none"> Is not according to required specifications Has been rejected by TEC and GC due to not suitable for cath lab dressing and poor adhesion M/S Tech zone was rejected by Holy Family Hospital, Rawalpindi in technical evaluation due to insufficient experience. M/s Tech zone donot have one year experience in said product. 	<ul style="list-style-type: none"> Item no. 60 Tape for skin hypoallergic adhesive is according to specification As PPRA Order No. L&M (PPRA) 540/2024/com dated. 15.10.2024, the GC accepted the product. Relevant documents provided As per bidding documents one year market experience is not mandatory for medical devices. 	Item no. 60 Tape for skin hypoallergic adhesive of M/s Tech zone accepted The grievance of M/S Anax Associates rejected




Dr. Iqra Munir,
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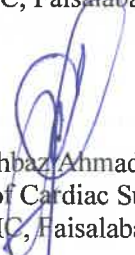
Engr. Sheraz Ali
Bio Medical Engineer
FIC, Faisalabad.




Mrs. Anila Saeed
Deputy Drug Controller,
FIC, Faisalabad.



Dr. Rehan Riaz
Assistant Prof. of Cardiology,
FIC, Faisalabad



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



Dr. Muhammad Nadeem
Medical Superintendent,
FIC, Faisalabad