MINUTES OF GRIEVANCE COMMITTEE MEETING FAISALABAD INSTITUTE OF CARDIOLOGY, FAISALABAD

A meeting of Grievance Committee for product of Drug/ Medicine& sutures, Angiography/Angioplasty, cardiac surgical disposable & CSSD items F.Y.2024-25 Re-tender II was held on 07-12-2024 at 11.00 am in the Office of the Medical Superintendent, Faisalabad Instituteof Cardiology, Faisalabad.

Drug/ Medicine& Sutures

1. M/S Mehran International

		A No No. 1 Address Co.					the letter and
	Item #	Item Name	Brand Name	Manufactured by	TAC Observations	GC Observation	Remarks
	5	BLOOD BAGS	Star Single	Suzhou Laishi	1. Free sale certificate	1. Relevant document	
П		450-500 ML	Blood Bag	Transfusion,	embassy attested not	attached	
1.72		(SINGLE)		CHINA	attached.		
						2. Experience of at least	
					2. Experience of at least	three years of public	Rejected
			4= 1		three years of public	sector institutions in	
					sector institutions in	name of bidder not	
					name of bidder not	attached	
					attached		

Angiography/Angioplasty items

1. M/s Tech Zone

1 1 1 1	em #	Item Name	Brand Name	Manufactured by	TAC Observations	GC Observation		Remarks/ Decision
	60	TAPE FOR SKIN	Natalie Care	Natalie Group,	Sufficient experience of			
		НҮРО		Malaysia	public sector	Relevant documents pro	ovided	Asserted
	1.	ALLERGIC			institutions not attached			Accepted
		ADHESIVE						

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(TRANSPARENT)	n"	5 ==	4.013
3" X 10 YARDS			

Cardiac Surgical disposable

1. M/s Tech Zone

Item #	Item Name	Brand Name	Manufactured by	TAC Observations	GC Observation Remarks/ Decision
51	DOTOTOTIL	Yafho	Hony Medical	Not User Friendly	With reference to PPRA order
	DRAPE/INCISE		China		no. L&M (PPRA)
	DRAPE WITH				540/2024/com dated Accepted
	ANTIMICROBIAL 45X60 CM				15.10.2024, the GC accepted
	ADULT				the product

2. M/s Saru International

Item #	Item Name	Brand Name	Manufactured by	TAC Observations	GC Observation	Remarks/ Decision
51	SURGICAL DRAPE/INCISE DRAPE WITH ANTIMICROBIAL 45X60 CM ADULT	3L Surgical Incise drape with Lodophor	Jiangxi 3L Medical products Group Co,Ltd, China	1. Sole agency agreement is not from at least previous one year 2. Sufficient experience of public	1. Relevant documents provided 2. Applied for Medical device registration (exemption for class B till 31 December 2024)	
				sector institutions not attached 3. Medical device registration not attached 4. Not user friendly	3. With reference to PPRA order no. L&M (PPRA) 540/2024/com dated 15.10,2024, the GC accepted the product	Accepted

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3. M/s Safeway Systems Pakistan

Item #	Item Name	Brand Name	Manufactured by	TAC Observations	GC Observation	Remarks/ Decision
33	One way vent	Cardiomed	NiproCananda	 Quality certification of 		
	Suction safety	Canada		CE not attached	1. Quality certification	
	device			Free sale certificate not	of CE not attached	
a de				attached	2. Free sale certificate	
				3. Sufficient experience o	f not attached	
= 7				public sector institute		
				not attached	3. Sufficient	1
				4. Invalid Sole agency	experience of	Rejected
				agreement attached	public sector	
				5. ISO 13485 not attached	institute not attaché	
				[투기 - 문화][[고 이 화 인상	해. 그 그래 왕기 회에 다른	
\$ 1					4. Relevant	
				[[] - 기타 - 기	documents	
					provided	
43.	Disposable full	Molnlycke	Health Care	Medical device	Medical device	
	body blanket		AB Sweden	registration not attached	registration not	
	adult			2. Quality certification of		
				CE not attached	2. Quality certification	
				3. Free sale certificate not	of CE not attached	
				attached	3. Free sale certificate	
				4. Experience of public	not attached	15. (2.)
				sector institute not	4. Experience of public	Rejected
				attached	sector institute not	
				5. Sole agency agreement	attached	
				not attached	5. Sole agency	
				6. ISO 13485 not attached		
				7. Sample not provided	attached	
					6. ISO 13485 not	
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44	Disposable full body blanket peads	Molnlycke	Health Care AB Sweden	4. 5. 6. 7.	Medical device registration not attached Quality certification of CE not attached Free sale certificate not attached Experience of public sector institute not attached Sole agency agreement not attached ISO 13485 not attached Sample not provided	3. 4. 5.	Medical device registration not attached Quality certification of CE not attached Free sale certificate not attached Experience of public sector institute not attached Sole agency agreement not attached ISO 13485 not attached Sample not provided	Rejected
54	Aortic cannula with connector straight (Adult) all sizes approved by FDA/CE	Cardiomed Canada	Nipro Cananda	C	Quality certification of E not attached Experience of public sector institute not attached Invalid sole agency agreement attached Invalid ISO 13485 attached	2.	Quality certification of CE not attached Experience of public sector institute not attached Relevant documents provided	Rejected
58	Pericardial sump with connector (Adult)	Cardiomed Canada	Nipro Cananda		Medical device registration not attached Quality certification of CE not attached Free sale certificate not	1. 2.	Medical device registration not attached Quality certification of CE not attached	Rejected

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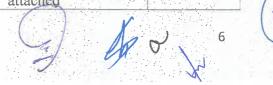




						2.454		
Si Si Te Si aj	Venous cannula ingle satge all izes (wire einforced, traight) adult pproved by DA/CE	Cardiomed Canada	Nipro Cananda	1. 2. 3. 4.	attached Experience of public sector institute not attached ISO 13485 not attached Medical device registration not attached Quality certification of CE not attached Sufficient experience of public sector institute not attached Invalid sole agency agreement attached Invalid ISO 13485 attached	1. 2. 3.	Experience of public sector institute not attached Relevant documents provided Medical device registration not attached	Rejected
si si re st ap F	Venous cannula ingle satge all izes (wire einforced, traight) peads pproved by DA/CE (18,20, 2, 24, 26 FR)	Cardiomed Canada	Nipro Cananda	3.	Quality certification of CE not attached Sufficient experience of public sector institute not attached Invalid Sole agency agreement attached Invalid ISO 13485 attached	2.	Quality certification of CE not attached Sufficient experience of public sector institute not attached Relevant documents provided	Rejected
	ucker nozzle dult	Cardiomed Canada	Nipro Cananda		Medical device registration not attached Quality certification of		Medical device registration not attached	Rejected

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			7	CE not attached	1.2.		
7,7=				3. Free sale certificate not		of CE not attached	
				attached	3.	Free sale certificate	
		-:-		4. Sufficient Experience		not attached	
		, =		of public sector	4.	Sufficient	
11.7				institute not attached		Experience of public	
1	₹* ⊻ =			5. Invalid Sole agency	·	sector institute not	
			24-	agreement attached		attached	
250			Da	6. ISO 13485 not attached	5.	Relevant documents	
					Ē.	provided	7 4 = 4 5
1 Mag							
9 000		8					
70	Sucker nozzle	Cardiomed	Nipro Cananda	Medical device	2 T		
	peads	Canada		registration not			
112				attached			
				2. Quality	= 1.	Medical device	
TUY 5		7/3		certification of CE		registration not	
		Tary and		not attached		attached	
pr 44.8+				3. Free sale certificate	2.	Quality certification	
				not attached		of CE not attached	
		1 100		4. Experience of	3.	Free sale certificate	
LF I			1. 1. 1. 1.	public sector	- >0	not attached	Rejected
				institute not	4.	Sufficient	
		la h		attached	7	Experience of public	
				5. Invalid Sole		sector institute not	
E SE, IS				agency agreement		attached	
N.				attached	5.	Relevant documents	
1 S. I.				6. ISO 13485 not		provided	
, Sa., \$	34			attached			
= 10 -				attacheu			
72	Surgical spring	Kardyva	Turkey	1. Medical device	1.	Medical device	
7.3	clip (Bull dog)			registration not attached		registration not	Rejected
				2. Quality certification of		attached	
				The control of a special stage of the first		The second secon	The state of the s



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	11. 13.		Matter to a 45			CE not attached	2.	Quality certification	
					3.	Free sale certificate not		of CE not attached	
		- 11				attached	3.	Free sale certificate	
ļ		THIS CO.			4.	Experience of public	PC I	not embassy attested	
						sector institute not	. 1 1:	attached	
				aT a		attached	4.	Experience of public	
					5.	Sole agency agreement	13 5	sector institute not	
1						not attached		attached	
1				4 4 4		ISO 13485 not attached	111		
1		Venous cannula	Cardiomed Nipro	Cananda		Medical device		Medical device	
1		two stage 36x50	Canada			registration not		registration not	
		FR approved by				attached		attached	
1		FDA/CE				2. Quality certification		2. Quality	
4						of CE not attached		certification of	
1						3. Free sale certificate		CE not attached	
				- 30		not attached		3. Free sale	
						4. Experience of		certificate not	
1	1= 1					public sector		embassy attested	
						institute not		attached	Rejected
						attached		4. Sufficient	
						5. Invalid Sole agency		Experience of	
-						agreement attached		public sector	
					1	6. ISO 13485 not		institute not	
	A. Bra					attached		attached	
1								5. Relevant	
							15 ² -4	documents	
1								provided	
					1.4°				

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4. M/S Medco Health care

ItemItem NameBrand NameManufactured byTAC ObservationsGC Oliver5 Chest DrainageRedaxRedax S.P.A.1. Free sale	servation Remarks/ Decision
5 Chart Drainage Paday Paday S.D.A. 1 Etracala	
Redax S.F.A, 1. Flee sale	
tube without trocar POGGIO certificate not	
(thoracic catheter RUSCO embassy	
right angled) all ITALY attested attached 1. Releva	t documents
sizes 2. Experience of provide	
public sector 2. Experi	nce of public
institute not sector	nstitute not Rejected
attached attache	
3. Sole agency 3. Sample	not provided
agreement not	
attached attached	
4. Sample not	
provided	

CSSD items

1. M/S Total technologies

Item #	Item Name	Brand Name	Manufactured by	TAC Observations	GC Observation	Remarks/ Decision
10	ETO Gas Cartridge	Kordon	Kordon	Sample not provided	Sample provided by firm and evaluated by GC	Accepted

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M/s Anax Associates (Pvt) Ltd

Sr.	Description	Firm Grievance	GC Observation	Remarks/ Decision
414		The firm claims that item no. 42		
		chlorhexidine gluconate 2% w/v dressing		The Grievance of M/S
= =1		8.5 cm x 11.5 cm is		Anax associate
Ē		Not DRAP registered in class D		rejected and item no.
	Grievance Against M/s	medical devices	The firm provided relevant	42 of M/s Techzone
	Techzone	It has been registered in Class A	documents	(chlorhexidine
		medical devices under the category		gluconate 2% w/v
		of catheter fixation dressing		dressing 8.5 cm x 11.5
				cm) accepted
		[- 얼마하다][라마 - 장마하 모임이 - 네 말!	[[상태] [[[[[[[[[[[[[[[[[[[

Mrs. Iqra Munir, Pharmacist, FIC, Faisalabad.

Dr. Rahan Riaz

Dr. Reman Riaz Assistant Prof. of Cardiology, FIC, Faisalabad Engr Sharaz Ali Bio Medical Engineer FIC, Faisalabad.

Dr. Shahbaz Ahmad Khiliji, Prof. of Cardiac Surgery, FIC, Faisalabad Mrs. Anila Saeed Deputy Drug Controller, FIC, Faisalabad.

Dr. Muhammad Fazal Ur Rehmanal Superintendent (Admin)
Medical Superintendent Medical Superintendent (Admin)
FIC, Faisalabad Faisalabad Institute of Cardiology
Faisalabad