

**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 Institute of Cardiology, Faisalabad.

**Drug/ Medicine & Sutures**

**1. M/S Mehran International**

Item #	Item Name	Brand Name	Manufactured by	TAC Observations	GC Observation	Remarks
5	BLOOD BAGS 450-500 ML (SINGLE)	Star Single Blood Bag	Suzhou Laishi Transfusion, CHINA	1. Free sale certificate embassy attested not attached.  2. Experience of at least three years of public sector institutions in name of bidder not attached	1. Relevant document attached  2. Experience of at least three years of public sector institutions in name of bidder not attached	Rejected

**Angiography/Angioplasty items**

**1. M/s Tech Zone**

Item #	Item Name	Brand Name	Manufactured by	TAC Observations	GC Observation	Remarks/ Decision
60	TAPE FOR SKIN HYPO ALLERGIC ADHESIVE	Natalie Care	Natalie Group, Malaysia	Sufficient experience of public sector institutions not attached	Relevant documents provided	Accepted



(TRANSPARENT) 3" X 10 YARDS					
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**Cardiac Surgical disposable**

**1. M/s Tech Zone**

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

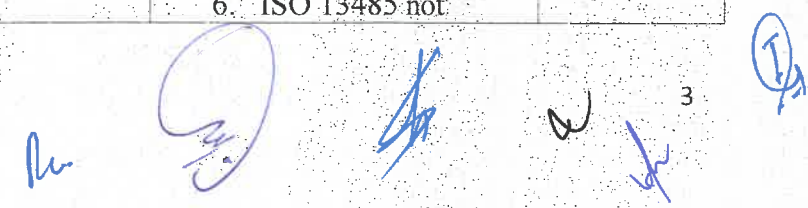
**2. M/s Saru International**

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 sector institutions not attached 3. Medical device registration not attached 4. Not user friendly	1. Relevant documents provided 2. Applied for Medical device registration (exemption for class B till 31 December 2024) 3. With reference to PPRA order no. L&M (PPRA) 540/2024/com dated 15.10.2024, the GC accepted the product	Accepted



3. M/s Safeway Systems Pakistan

Item #	Item Name	Brand Name	Manufactured by	TAC Observations	GC Observation	Remarks/ Decision
33	One way vent Suction safety device	Cardiomed Canada	NiproCanada	<ol style="list-style-type: none"> <li>1. Quality certification of CE not attached</li> <li>2. Free sale certificate not attached</li> <li>3. Sufficient experience of public sector institute not attached</li> <li>4. Invalid Sole agency agreement attached</li> <li>5. ISO 13485 not attached</li> </ol>	<ol style="list-style-type: none"> <li>1. Quality certification of CE not attached</li> <li>2. Free sale certificate not attached</li> <li>3. Sufficient experience of public sector institute not attached</li> <li>4. Relevant documents provided</li> </ol>	Rejected
43	Disposable full body blanket adult	Molnlycke	Health Care AB Sweden	<ol style="list-style-type: none"> <li>1. Medical device registration not attached</li> <li>2. Quality certification of CE not attached</li> <li>3. Free sale certificate not attached</li> <li>4. Experience of public sector institute not attached</li> <li>5. Sole agency agreement not attached</li> <li>6. ISO 13485 not attached</li> <li>7. Sample not provided</li> </ol>	<ol style="list-style-type: none"> <li>1. Medical device registration not attached</li> <li>2. Quality certification of CE not attached</li> <li>3. Free sale certificate not attached</li> <li>4. Experience of public sector institute not attached</li> <li>5. Sole agency agreement not attached</li> <li>6. ISO 13485 not</li> </ol>	Rejected



					attached	
44	Disposable full body blanket pads	Molnlycke	Health Care AB Sweden	<ol style="list-style-type: none"> <li>1. Medical device registration not attached</li> <li>2. Quality certification of CE not attached</li> <li>3. Free sale certificate not attached</li> <li>4. Experience of public sector institute not attached</li> <li>5. Sole agency agreement not attached</li> <li>6. ISO 13485 not attached</li> <li>7. Sample not provided</li> </ol>	<ol style="list-style-type: none"> <li>1. Medical device registration not attached</li> <li>2. Quality certification of CE not attached</li> <li>3. Free sale certificate not attached</li> <li>4. Experience of public sector institute not attached</li> <li>5. Sole agency agreement not attached</li> <li>6. ISO 13485 not attached</li> <li>7. Sample not provided</li> </ol>	Rejected
54	Aortic cannula with connector straight (Adult) all sizes approved by FDA/CE	Cardiomed Canada	Nipro Canada	<ol style="list-style-type: none"> <li>1. Quality certification of CE not attached</li> <li>2. Experience of public sector institute not attached</li> <li>3. Invalid sole agency agreement attached</li> <li>4. Invalid ISO 13485 attached</li> </ol>	<ol style="list-style-type: none"> <li>1. Quality certification of CE not attached</li> <li>2. Experience of public sector institute not attached</li> <li>3. Relevant documents provided</li> </ol>	Rejected
58	Pericardial sump with connector (Adult)	Cardiomed Canada	Nipro Canada	<ol style="list-style-type: none"> <li>1. Medical device registration not attached</li> <li>2. Quality certification of CE not attached</li> <li>3. Free sale certificate not</li> </ol>	<ol style="list-style-type: none"> <li>1. Medical device registration not attached</li> <li>2. Quality certification of CE not attached</li> </ol>	Rejected

				<ul style="list-style-type: none"> <li>4. Experience of public sector institute not attached</li> <li>5. ISO 13485 not attached</li> </ul>	<ul style="list-style-type: none"> <li>3. Free sale certificate not attached</li> <li>4. Sufficient Experience of public sector institute not attached</li> <li>5. Relevant documents provided</li> </ul>	
65	Venous cannula single satge all sizes (wire reinforced, straight) adult approved by FDA/CE	Cardiomed Canada	Nipro Cananda	<ul style="list-style-type: none"> <li>1. Medical device registration not attached</li> <li>2. Quality certification of CE not attached</li> <li>3. Sufficient experience of public sector institute not attached</li> <li>4. Invalid sole agency agreement attached</li> <li>5. Invalid ISO 13485 attached</li> </ul>	<ul style="list-style-type: none"> <li>1. Medical device registration not attached</li> <li>2. Quality certification of CE not attached</li> <li>3. Sufficient experience of public sector institute not attached</li> <li>4. Relevant documents provided</li> </ul>	Rejected
66	Venous cannula single satge all sizes (wire reinforced, straight) peads approved by FDA/CE (18,20, 22, 24, 26 FR)	Cardiomed Canada	Nipro Cananda	<ul style="list-style-type: none"> <li>1. Quality certification of CE not attached</li> <li>2. Sufficient experience of public sector institute not attached</li> <li>3. Invalid Sole agency agreement attached</li> <li>4. Invalid ISO 13485 attached</li> </ul>	<ul style="list-style-type: none"> <li>1. Quality certification of CE not attached</li> <li>2. Sufficient experience of public sector institute not attached</li> <li>3. Relevant documents provided</li> </ul>	Rejected
69	Sucker nozzle adult	Cardiomed Canada	Nipro Cananda	<ul style="list-style-type: none"> <li>1. Medical device registration not attached</li> <li>2. Quality certification of</li> </ul>	<ul style="list-style-type: none"> <li>1. Medical device registration not attached</li> </ul>	Rejected



				<ul style="list-style-type: none"> <li>CE not attached</li> <li>3. Free sale certificate not attached</li> <li>4. Sufficient Experience of public sector institute not attached</li> <li>5. Invalid Sole agency agreement attached</li> <li>6. ISO 13485 not attached</li> </ul>	<ul style="list-style-type: none"> <li>2. Quality certification of CE not attached</li> <li>3. Free sale certificate not attached</li> <li>4. Sufficient Experience of public sector institute not attached</li> <li>5. Relevant documents provided</li> </ul>	
70	Sucker nozzle peds	Cardiomed Canada	Nipro Canada	<ul style="list-style-type: none"> <li>1. Medical device registration not attached</li> <li>2. Quality certification of CE not attached</li> <li>3. Free sale certificate not attached</li> <li>4. Experience of public sector institute not attached</li> <li>5. Invalid Sole agency agreement attached</li> <li>6. ISO 13485 not attached</li> </ul>	<ul style="list-style-type: none"> <li>1. Medical device registration not attached</li> <li>2. Quality certification of CE not attached</li> <li>3. Free sale certificate not attached</li> <li>4. Sufficient Experience of public sector institute not attached</li> <li>5. Relevant documents provided</li> </ul>	Rejected
72	Surgical spring clip (Bull dog)	Kardyva	Turkey	<ul style="list-style-type: none"> <li>1. Medical device registration not attached</li> <li>2. Quality certification of</li> </ul>	<ul style="list-style-type: none"> <li>1. Medical device registration not attached</li> </ul>	Rejected

				<ul style="list-style-type: none"> <li>CE not attached</li> <li>3. Free sale certificate not attached</li> <li>4. Experience of public sector institute not attached</li> <li>5. Sole agency agreement not attached</li> <li>6. ISO 13485 not attached</li> </ul>	<ul style="list-style-type: none"> <li>2. Quality certification of CE not attached</li> <li>3. Free sale certificate not embassy attested attached</li> <li>4. Experience of public sector institute not attached</li> </ul>	
	Venous cannula two stage 36x50 FR approved by FDA/CE	Cardiomed Canada	Nipro Canada	<ul style="list-style-type: none"> <li>1. Medical device registration not attached</li> <li>2. Quality certification of CE not attached</li> <li>3. Free sale certificate not attached</li> <li>4. Experience of public sector institute not attached</li> <li>5. Invalid Sole agency agreement attached</li> <li>6. ISO 13485 not attached</li> </ul>	<ul style="list-style-type: none"> <li>1. Medical device registration not attached</li> <li>2. Quality certification of CE not attached</li> <li>3. Free sale certificate not embassy attested attached</li> <li>4. Sufficient Experience of public sector institute not attached</li> <li>5. Relevant documents provided</li> </ul>	Rejected

4. M/S Medco Health care

Item #	Item Name	Brand Name	Manufactured by	TAC Observations	GC Observation	Remarks/ Decision
5	Chest Drainage tube without trocar (thoracic catheter right angled) all sizes	Redax	Redax S.P.A, POGGIO RUSCO ITALY	<ol style="list-style-type: none"> <li>Free sale certificate not embassy attested attached</li> <li>Experience of public sector institute not attached</li> <li>Sole agency agreement not attached</li> <li>Sample not provided</li> </ol>	<ol style="list-style-type: none"> <li>Relevant documents provided</li> <li>Experience of public sector institute not attached</li> <li>Sample not provided</li> </ol>	Rejected

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

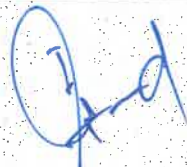
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M/s Anax Associates (Pvt) Ltd

Sr.	Description	Firm Grievance	GC Observation	Remarks/ Decision
1	Grievance Against M/s Techzone	<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"> <li>• Not DRAP registered in class D medical devices</li> <li>• It has been registered in Class A medical devices under the category of catheter fixation dressing</li> </ul>	The firm provided relevant documents	The Grievance of M/S Anax associate rejected and item no. 42 of M/s Techzone (chlorhexidine gluconate 2% w/v dressing 8.5 cm x 11.5 cm) accepted



Mrs. Iqra Munir,  
Pharmacist,  
FIC, Faisalabad.



Engr. Sharaz Ali  
Bio Medical Engineer  
FIC, Faisalabad.



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



Dr. Rehman Riaz,  
Assistant Prof. of Cardiology,  
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Dr. Shahbaz Ahmad Khiliji,  
Prof. of Cardiac Surgery,  
FIC, Faisalabad.



Dr. Muhammad Fazal Ur Rehman,  
Medical Superintendent,  
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