MINUTES OF GRIEVANCE COMMITTEE MEETING
FAISALABAD INSTITUTE OF CARDIOLOGY, FAISALABAD

A meeting of Grievance Committee for product of Cardiac Surgical Disposables F.Y.2025-26 Re-tender was held on 03-12-2025 at 10:30 am in the Office of the Medical Superintendent, Faisalabad Institute of Cardiology, Faisalabad.

Cardiac Surgical Disposables

3. M/S Alpha labs

Company Grievance	TAC Observation	Grievance Decision	Remarks
Dear Sir, With reference to the Evaluation Report published on the PPRA portal for Cardiac Surgical &Disposables Items, our bid was declared non-compliant. Kindly find our point-wise clarification below: Item 41 – Surface Disinfectant Medical Device Registration HiClean Advance+ Surface Disinfectant is not classified as a Medical Device under DRAP, as supported by the submitted statement and copy of DRAP rules. Experience of Product The product has been in use for over one year in reputable public and private institutions. It was initially introduced through our joint company, Medinostic Health Care (Pvt.) Ltd.; therefore, POs in their name are valid experience. Free Sales Certificate Not applicable, as we are the manufacturer. Sole Agency Agreement Not applicable, as we are the manufacturer. Quality Certificate CE and ISO 13485 Certificates were submitted and are reattached. ISO Certificate Valid ISO certificates were already submitted and are reattached. All required document	**Item no 41** **Surface Disinfectant 5Ltr (DRAP REGISTERED IF APPLICABLE)** • Medical device registration not attached • Experience of product at least one year not attached • Free sale certificate not attached • Sole agency agreement not attached • Quality certificate not attached • ISO certificate not attached	• Experience of product at least one year not attached • Sole agency agreement issued by foreign principals not attached • Quality certificate not attached	Rejected

Dr. Rehan Riaz,
Associate Professor of Cardiology,
F.I.C. Faisalabad.

Dr. Rashid Ali Malik,
Assistant Professor of Cardiac Surgery,
F.I.C. Faisalabad.

Dr. Fazal-ur-Rehman,
DMS General Stores,
F.I.C. Faisalabad.

Mrs. Iqra Munir,
Pharmacist, F.I.C. Faisalabad

Mr. Sharaz Ali,
Bio Medical Engineer, F.I.C. Faisalabad

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Cardiac Surgical Disposables

5. M/S Anax Associates

Company Grievance	TAC Observation	Grievance Decision	Remarks
We, M/s Anax Associates (Pvt.) Ltd., respectfully submit this grievance regarding the technical evaluation of the Re-Tender for Cardiac Surgery Disposable Items for the year 2025–26. We seek a fair reconsideration of our technical status, as we believe our disqualification may have resulted from a misunderstanding of regulatory requirements. About Our Company M/s Anax Associates (Pvt.) Ltd. is the sole DRAP-registered manufacturer in Pakistan producing surgical and non-surgical face masks, PPE surgical gowns, and surgical drapes under DRAP Manufacturing License No. ELM-0071. Our "Medpro" brand includes products manufactured locally with strict adherence to quality, safety, and internationally recognized standards. Grounds for Our Grievance We have been declared technically not qualified for the following tender items: • Item No. 10: Medpro Disposable Caps (Female) • Item No. 11: Medpro Disposable Caps (Male) • Item No. 12: Medpro Disposable Patient Kits According to the evaluation, Clarification on DRAP Requirements The items mentioned above—disposable caps (male/female) and disposable patient kits—are non-sterile disposable products. As per DRAP Pakistan guidelines, non-sterile items do NOT require drape registration, and therefore, the absence of such registration cannot be considered a technical non-compliance. All	**Item no 10** **Disposable Caps Female** • Medical device registration not attached • Experience of product at least one year not attached • Invalid GMP certificate attached **Item no 11** **Disposable Caps Male** • Medical device registration not attached • Experience of product at least one year not attached • Invalid GMP certificate attached **Item no 13** **Disposable Patient Kit** • Medical device registration not attached • Experience of product at least one year not attached • Invalid GMP certificate attached	Relevant documents provided Relevant documents provided Medical device registration not attached	Accepted Accepted Rejected

required documentation to demonstrate manufacturing authorization, product conformity, and compliance with tender specifications was duly submitted. Request for Reconsideration In light of the above, we humbly request the honorable Evaluation Committee to: 1. Re-evaluate our technical documents for Items 10, 11, and 12. 2. Recognize that drape registration is not applicable to these non-sterile products. 3. Restore our technical qualification status in accordance with DRAP regulations and tender criteria. 4. Provide an opportunity for additional clarification, if required. We assure you of our full cooperation and commitment to meeting all regulatory requirements			

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Cardiac Surgical Disposables

2. M/S Angels Enterprises

Company Grievance	TAC Observation	Grievance Decision	Remarks
We refer to the 2025–2026 tender conducted by FIC Faisalabad for hand disinfectant products. It has come to our attention that our product Sterillium Hand Disinfectant was technically disqualified due to DRAP registration status. Sir, we would like to submit that on 18-11-2016 we filed our application with DRAP Pakistan under the Health & OTC Division along with all required documents and the applicable fee for the registration of our hand disinfectant Sterillium. After almost seven years DRAP informed us that hand disinfectant does not fall under the Health & OTC category and that it should instead be submitted under the Medical Devices or Medicated Cosmetics Division. Accordingly, we resubmitted our complete documentation and fee to DRAP once again on 13-10-2023. It is unfortunate that DRAP has still not been able to determine the appropriate category for imported hand sanitizers. Furthermore, while local manufacturers are required to obtain registration from the Pakistan Standards Quality control Council.	**Item no 16** **Hand Disinfectant-Sterillium** • Medical device registration not attached • Experience of product at least one year not attached	Rule of DRAP registration not applicable for Hand disinfectants.	Accepted

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Cardiac Surgical Disposables

4. M/S Mehran International

Company Grievance	TAC Observation	Grievance Decision	Remarks
To, Medical Superintendent, Faisalabad Institute of Cardiology, Faisalabad. Subject: Grievance & Request for Re-evaluation – Tender Item No. 12 (Disposable Dignity Sheet) Respected Sir/Madam, With due respect, we would like to submit a formal grievance regarding Tender Item No. 12 – Disposable Dignity Sheet, in which our company, Mehran International, has been marked as non-responsive. We would like to clarify that: Mehran International possesses a valid Agency Agreement for the quoted product. We are hereby resubmitting the physical copy of the agreement for your kind review and record. The experience certificates from private institutes are duly attached, and we are resubmitting the copies for consideration. The Free Sales Certificate is also being submitted again for re-evaluation, as required. In light of the above, we respectfully request your good office to: Kindly re-evaluate all the submitted documents	**Item no 12** **Disposable Dignity Sheet** • Free Sale certificate not attached • Experience of product at least one year not attached • Ambiguity in authority letter	• Free Sale certificate not attached • Experience of product at least one year not attached. • Ambiguity in authority letter	Rejected

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Cardiac Surgical Disposables

1. **M/S Safeway Systems Pakistan**

Company Grievance	TAC Observation	Grievance Decision	Remarks
The Medical Superintendent Faisalabad Institute of Cardiology Faisalabad Subject: Grievance Against Technical Evaluation Cardiac Surgical Disposable Items (2025–2026 RE-Tender) Respected Sir, This is to submit a grievance regarding the "Minutes of Technical Evaluation Committee Meeting – Cardiac Surgical Disposable Items (2025–2026 RE-Tender)" uploaded on 22-11-2025. Item 30 – Oxygenator (Neonatal) Sr. No Technical Observation Justification 1 Invalid Free Sale Certificate Valid Free Sales certificate Attached 2 Name of importer on FSC of tubing mentioned as M/s Medica Importer of the tubing is M/S Medica. Since the main tender demand is the Oxygenator and tubing pack is its accessory, and the tubing made by SasanSağlık (Türkiye) is specifically required by the end user, we have been quoting the same configuration for the last 3 years. Supply orders from previous years of FIC and CPEIC Multan are attached	**Item no 30** **Oxygenator membrane with low priming volume for neonates** • Invalid Free sale certificate attached • Name of importer on free sale certificate of tubing MS Medica mentioned • Invalid EC Certificate of tubing attached • Invalid ISO certificate of Oxygenator and tubing attached • Name of importer on medical device registration of tubing of M/S Medica mentioned • Name of manufacturer of custom tubing not mentioned on technical bid **Item no 42** **Venous cannula single stage all sizes Peads** • Medical device registration not attached • Quality certificate not attached • Experience of product at least one year not attached	• Name of importer on free sale certificate of tubing MS Medica mentioned • Name of importer on medical device registration of tubing M/S Medica mentioned • Name of manufacturer of custom tubing not mentioned on technical bid • Application for renewal of Medical Device registaretion attached • Quality certificate not attached	Rejected Rejected

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Cardiac Surgical Disposables

Company Grievance	TAC Observation	Grievance Decision	Remarks
Item 42 – Venous Cannula (Pediatric, Wire Reinforced) Sr. No Technical Observations Justifications 1 MDR Not Attached MDR Attached 2 Quality Certificate Not Attached MDSAP, ISO Attached 3 One Year Experience Not Attached FIC, MIC EXP Attached Item 51 – Venous Cannula (Adult, Angled Metal Tip) Sr. No Technical Observations Justifications 1 Quality Certificate Not Attached MDSAP, ISO Attached 2 Invalid Medical Device Registration Renewal Submitted and copy attached 3 Manufacturer Name Mismatch Legal Name change letter Attached By Manufacturer Item 52 – Cardioplegia Delivery System Sr. No Technical Observations Justifications 1 Invalid Free Sales Valid FSC Attached 2 Invalid ISO Attached Valid ISO Attached 3 Invalid Sole Agency Fresh Sole Agency Attached.	**Item no 51** **Venous cannula single stage Adult all sizes** • Quality certificate not attached • Invalid Medical device registration certificate attached • Name of manufacturer M/S Cardiomed Supplies on medical device registration while M/S Nipro Canada on technical bid mentioned **Item no 52** **Cardioplegia delivery system** • Invalid free sale certificate attached • Invalid sole agency agreement attached • Invalid ISO certificate attached	• Quality certificate not attached • Application for renewal of Medical Device registaretion attached • Name of manufacturer M/S Cardiomed Supplies on medical device registration while M/S Nipro Canada on technical bid mentioned • Relevant Documents provided	Rejected Accepted

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