MOM OF GRIEVANCE REDRESSAL COMMITTEE FOR THE PROCUREMENT OF DIALYSIS ITEMS FOR FY 2025-26

Sr. No.	Inq.	Generic Name	Bidder / Importer / Sole Agent	Quoted Brand	Manufactured by	Final Status (Responsive/ Non-Responsive)	Reason(s) for Rejection	Grievance of the firm	Remarks
1	3	**AV Set Blood Tubing lining**	Fresenius Medical Care Pakistan Pvt. Ltd.	Fresline/ Malaysia	Vital Healthcare SDN, BHD	**Responsive**	Compliant	Grievance of the firm M/s Renacon Pharma Ltd. Against Fresenius Medical Care Pakistan Pvt. Ltd. We would like to submit our grievance regarding the Technical Evaluation Report of Blood Tubing Line 6.3mm with one Transducer Protector (Fluid Barrier) & Pre-Pump Arterial Pressure Monitoring Line (Individually Sterile Packed).It has been observed that the bid submitted by M/s Fresenius Medical Care Pakistan has been declared technically responsive. However, certain discrepancies appear in the mandatory documentary evidence submitted by the firm, which are respectfully brought to your kind attention for review. 1. ISO 13485 Certificate - Manufacturer Address Discrepancy The manufacturer's address mentioned on the ISO 13485 certificate does not correspond with the address mentioned on the Enlistment Certificate of the product.This difference creates inconsistency in the identification of the actual manufacturing facility and raises concerns regarding compliance with the tender requirement that supporting certificates must clearly correspond with the registered/enlisted manufacturer details. 2. EC Certificate - Manufacturer	**<u>Grievance of the firm M/s Renacon Pharma Ltd. Against Fresenius Medical Care Pakistan Pvt. Ltd.</u>** Mr. M. Asim Raza attended the meeting on the behalf of M/s Renacon Pharma Ltd and Mr. M. Sohail attended the meeting on the behalf M/s Fresenius Medical Care Pakistan Pvt. Ltd. The committee heard the viewpoints of both firms and found that the provided documents regarding change of address of the manufacturer that is form-7 and application for renewal by M/s Fresenius Medical Care Pakistan Pvt. Ltd. duly verified the claim and found compliant with advertised technical criteria. So, the grievance of M/s Renacon Pharma Ltd was rejected against Fresenius Medical Care Pakistan Pvt. Ltd. and upheld the decision of the technical evaluation committee. Hence, the status of quoted item remained **Responsive**. **<u>Grievance of M/s Hoora Pharma against M/s Fresenius Medical Care Pakistan Pvt. Ltd:</u>** Mr. M. Ahmed attended the meeting on the behalf of M/s Hoora Pharma and Mr.M. Sohail attended the meeting on the behalf M/s Fresenius Medical Care Pakistan Pvt. Ltd. The committee heard the viewpoints of both firms and found that the provided documents regarding change of address of the manufacturer that is form-7 and application for renewal by M/s Fresenius Medical Care Pakistan Pvt. Ltd. duly verified the claim and

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								Address Discrepancy Similarly, the manufacturer's address reflected on the EC Certificate also differs from the address mentioned on the Enlistment Certificate. This discrepancy further raises questions regarding the uniformity and authenticity of the manufacturer details provided in the bid documents. As per tender requirements, the manufacturer information across all mandatory certificates should correspond with the enlistment/registration documentation to ensure clarity regarding the approved manufacturing facility. In light of the above observations, it is respectfully requested that the evaluation committee may kindly: * Re-examine the ISO 13485 certificate and EC certificate submitted by M/s Fresenius, specifically with regard to the manufacturer's address. * Verify the manufacturer details against the Enlistment Certificate and related registration documentation to ensure consistency. * Reassess the technical responsiveness of the quoted item in accordance with the tender requirements and evaluation criteria.* Strict adherence to the tender conditions is essential to	found compliant with advertised technical criteria. So, the grievance of M/s Hoora Pharma Ltd was rejected against Fresenius Medical Care Pakistan Pvt. Ltd. and upheld the decision of the technical evaluation committee. Hence, the status of quoted item remained **Responsive.**

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								maintain transparency, fairness, and equal treatment for all participating bidders. Allowing discrepancies in mandatory documentation may inadvertently affect the integrity of the procurement process. Grievance of M/s Hoora Pharma against M/s Fresenius Medical Care Pakistan Pvt. Ltd: Please reject both offers as the Same brand and manufacturer quoted by two bidders, please verify the Agency agreement dully embassy attested / Apostille Please verify the Registration of Foreign Manufacturer with Regulatory Authority of the Country of Manufacturer for the Quoted Product. Please verify quoted Brand name in FSC and other quality certificates	
2	**1**	**AVF Needle 16G (Pairs)**	Renacon Pharma Ltd.	Renav/ China	Jiangxi Sanxin Medtec Co. Ltd	**Non-Responsive**	1. Quoted Brand name(Renav) not mentioned on attached free sale certificate.	With reference to the Technical Evaluation Report issued by your office, we would like to respectfully bring to your kind consideration that the following quoted products from our company have been declared Non-Responsive on the grounds that the quoted brand name is not mentioned on the attached Free Sale Certificate (FSC): * Item No. 01 - AVF Needle 16G (Renav) Item No. 02 - AVF Needle 17G (Renav)	Mr. M. Asim Raza from M/s Renacon Pharma Ltd.. attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Technical Evaluation Criteria and announced Technical Evaluation Report. The committee after due deliberation and discussion decided that: 1. The quoted brand name did not mention on attached free sale certificate of the quoted item, which is contrary to advertised evaluation criteria. hence grievance of the firm was not accepted to the extent of this

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Sr. No.	Inq.	Generic Name	Bidder / Importer / Sole Agent	Quoted Brand	Manufactured by	Final Status (Responsive/ Non-Responsive)	Reason(s) for Rejection	Grievance of the firm	Remarks
								Item No. 03 - AV Set Blood Tubing Line (Rena-Line) We would like to respectfully submit that the evaluation committee's decision has caused serious concern for us because the samedocuments and regulatory certifications were accepted and qualified in the previous tender, and our products were declared technically responsive at that time.It appears that there may be some misunderstanding regarding the regulatory framework of China, from where these medical devices are manufactured and exported in finished form. As per the regulatory practice of the manufacturing country, Free Sale Certificates (FS) and export registrations are issued based on the product category or device registration/classification rather than individual commercial brand names. For your kind clarification, the following details are provided: The Blood Tubing Line and AV Fistula Needle Set are registered medical devices in China under the National Medical Products Administration (NMPA). The respective registration numbers are: * Blood Tubing Line: NMPA Registration No. 20203100815 AV Fistula Needle Set: NMPA Registration No. 20233100210	parameter. 2. The provided ISO 9001 of the firm did not cover the scope of quoted item hence nor marks were awarded to the extent of this parameter. Hence, the status of the quoted item remained **Non-Responsive.**
3	**2**	**AVF Needle 17G (Pairs)**	Renacon Pharma Ltd.	Renav/ china	Jiangxi Sanxin Medtec Co. Ltd	**Non-Responsive**	1. Quoted Brand name(Renav) not mentioned on attached free sale certificate.		1. The quoted brand name did not mention on attached free sale certificate of the quoted item hence grievance of the firm was not accepted to the extent of this parameter. 2. The provided ISO 9001 of the firm did not cover the scope of quoted item hence nor marks were awarded to the extent of this parameter. Hence, the status of the quoted item remained **Non-Responsive.**
4	**3**	**AV Set Blood Tubing lining**	Renacon Pharma Ltd.	Rena-Line/china	Jiangxi Sanxin Medtec Co. Ltd	**Non-Responsive**	1. Quoted Brand name(Renaline) not mentioned on attached free sale certificate.		1. The quoted brand name did not mention on attached free sale certificate of the quoted item hence grievance of the firm was not accepted to the extent of this parameter. 2. The provided ISO 9001 of the firm did not cover the scope of quoted item hence nor marks were awarded to the extent of this parameter. Hence, the status of the quoted item remained **Non-Responsive.** **<u>Grievance of M/s Hoora Pharma (Pvt.) Ltd against M/s Renacon Pharma Pvt. Ltd.</u>** Mr. M. Ahmed attended the meeting on the behalf of M/s Hoora Pharma (Pvt.) Ltd and

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Sr. No.	Inq.	Generic Name	Bidder / Importer / Sole Agent	Quoted Brand	Manufactured by	Final Status (Responsive/ Non-Responsive)	Reason(s) for Rejection	Grievance of the firm	Remarks
								Under Chinese regulatory practice, the Free Sale Certificate reflects the standardized product registration or device category rather than the commercial brand name used for marketing and distribution. For commercial and marketing purposes, the following brand names are used: Renav - Brand name for AV Fistula Needie Rena-Line - Brand name for Blood Tubing Line. Both products fall under the above-mentioned registered medical device categories.Therefore, the difference between the FSC details and the brand names mentioned in labeling and marketing is purely due to the regulatory practice of issuing certificates under generic device classification instead of brand-specific identification.For further clarification, we are also attaching a confirmation letter from our principal/manufacturer, explaining the regulatory practice and confirming that the above-mentioned brand names correspond to the registered products. In light of the above facts and supporting documentation, we humbly request your good office to: Reconsider and accept our grievance, and Re-evaluate the submitted documents, and Revise the status of our quoted products from Non-Responsive to	Mr. .M. Asim Raza attended the meeting on the behalf M/s Renacon Pharma Pvt. Ltd The committee heard the viewpoints of both firms. The provided free sale certuficate of M/s Renacon Pharma Pvt. Ltd is not accepted and the firm is aleady non-responsive in its own grievance. Hence, the GRC upheld the decision of the technical evaluation committee and status remained **Non-Responsive.**

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Sr. No.	Inq.	Generic Name	Bidder / Importer / Sole Agent	Quoted Brand	Manufactured by	Final Status (Responsive/ Non-Responsive)	Reason(s) for Rejection	Grievance of the firm	Remarks
								Responsive, in the interest of transparency and fair competition. Valid ISO 9001: ISO 9001 certification (Certificate No. PK07/00329) is valid and issued by a certification body acredited under the International Acreditation Forum (IAF) framework. As per the tender/evaluation criteria, certifications acredited by IAF certification be granted accordingly. Online verification of the certificate can also be requirement and remains valid. Therefore, we kindly request that the allocated 2 marks for ISO 9001 E-mail: info @renaconpharma.com www.renaconpharma.com provided, if required, for your review and confirmation. We remain fully committed to supplying high-quality medical devices in compliance with all regulatory requirements and procurement guidelines. We shall be grateful for your kind reconsideration and favorable decision. Grievance of M/s Hoora Pharma (Pvt.) Ltd against M/s Renacon Pharma Pvt. Ltd. Blood Tube lining: *Please verify the Registration of Foreign Manufacturer with Regulatory Authority of the Country of Manufacturer for the Quoted Product. *Please verify quoted	

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Sr. No.	Inq.	Generic Name	Bidder / Importer / Sole Agent	Quoted Brand	Manufactured by	Final Status (Responsive/ Non-Responsive)	Reason(s) for Rejection	Grievance of the firm	Remarks
								Brand name in FSC and other quality certificates. AV Fistula needle 16G & 17G *Please verify the Registration of Foreign Manufacturer with Regulatory Authority of the Country of Manufacturer for the Quoted Product *Please verify quoted Brand name in FSC and other quality certificates	

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Sr. No.	Inq.	Generic Name	Bidder / Importer / Sole Agent	Quoted Brand	Manufactured by	Final Status (Responsive/ Non-Responsive)	Reason(s) for Rejection	Grievance of the firm	Remarks
5	**1**	**AVF Needle 16G (Pairs)**	Hoora Pharma (Pvt.) Ltd	Nipro AVF/indonesia	Nipro Indonesia	**Non-Responsive**	1.On attached Sole Agency Agreement Manufacturer address is not as per attached enlistment certificate and Appostile and Notrial Certificate attached is not of country of manufacturer / origin) 2.Bidder name is not mentioned as importer on submitted sample, Establishment license no and enlistment , certificate no.not mentioned on submitted sample 3.Attached ISO 13485 could not verified online 4.Registration of Foreign Manufacturer with Regulatory Authority of the Country of Manufacturer for the Quoted Product not attached 5. Attached Enlistment Certificate is not on the name of bidder 6.Attached Quality	Valid Sole Agency Agreement is already attached with technical bid & same is attached herewith for your reference. There is no terms in bid conditions Attached ISO 13485 is online accessible & online verification is already shared with concerned person Same is attached herewith for your reference Attached Purchase orders are already attached with our bid Same are attached herewith for your reference CE Certificates along with extensions letter from relevant regulatory body is already attached with our bid & also note that the only valid certificates could be online verified. When certificate is expired, the regulatory body removes from their website. Same is attached herewith for your reference (Could be verified through email from regulatory body) Certificate is attached herewith for your reference. GD's of quoted items along with all relevant documents are attached herewith for your reference Free sale certificate is already attached with our bid Same is attached herewith for your reference	Mr. M. Ahmed from M/s Hoora Pharma (Pvt.) Ltd. attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Technical Evaluation Criteria and announced Technical Evaluation Report. The committee after due deliberation and discussion decided that: 1. The firm did not provide any additional document regarding objection on attached Sole Agency Agreement. The grievance of the firm was not accepted to the extent of this parameter. 2. Bidder name was not mentioned as importer, Establishment license No. and Enlistment, Certificate No. not mentioned on submitted sample. The grievance of the firm was not accepted to the extent of this parameter. 3. The firm provided the ISO 13485 that was online verified. The grievance of the firm was accepted to the extent of this parameter. 4. The firm did not provided Registration of Foreign Manufacturer with Regulatory Authority of the Country of Manufacturer for the Quoted Product. The grievance of the firm was not accepted to the extent of this parameter. 5. The attached Enlistment Certificate is not on the name of bidder. The grievance of the firm was not accepted to the extent of this parameter. 6. The attached Quality Compliance Standards (JpMHLW/ CE MDD/MDR/ US FDA 510 K/ Prequalified by WHO (Certificate) of Quoted Item was expired and

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Sr. No.	Inq.	Generic Name	Bidder / Importer / Sole Agent	Quoted Brand	Manufactured by	Final Status (Responsive/ Non-Responsive)	Reason(s) for Rejection	Grievance of the firm	Remarks
							Compliance Standards (JpMHLW/ CE MDD/MDR/ US FDA 510 K/ Prequalified by WHO (Certificate) of Quoted Item is expired and could not be verified online. 7.Undertaking/Any document not attached regarding Required Storage Temperature as per Product's Requirement 8. Goods Declaration Certificates of Quoted Items Along with all Relevant Documents such as Bill of Lading / Airway Bill, Commercial Invoice and Packing List not attached 9.Attached free sale certificate is not valid (Not notarized/ apostille certification not attached		could not be verified online. The grievance of the firm was not accepted to the extent of this parameter. 7. The firm did not provide undertaking/Any document regarding Required Storage Temperature as per Product's Requirement. The grievance of the firm was not accepted to the extent of this parameter. 8. The firm did not provide Goods Declaration Certificates of Quoted Items Along with all Relevant Documents such as Bill of Lading / Airway Bill, Commercial Invoice and Packing List. The grievance of the firm was not accepted to the extent of this parameter. 9. The firm did not provide valid Free Sales Certificate(Not notarized/ apostille certification not attached). The grievance of the firm was not accepted to the extent of this parameter. Hence the Status of the quoted item (AV Fistula needle 16G & 17G) remained **"Non -Responsive"**

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Sr. No.	Inq.	Generic Name	Bidder / Importer / Sole Agent	Quoted Brand	Manufactured by	Final Status (Responsive/ Non-Responsive)	Reason(s) for Rejection	Grievance of the firm	Remarks
6	**2**	**AVF Needle 17G (Pairs)**	Hoora Pharma (Pvt.) Ltd	Nipro AVF/indonesia	Nipro Indonesia	**Non-Responsive**	1.On attached Sole Agency Agreement Manufacturer address is not as per attached enlistment certificate and Appostile and Notrial Certificate attached is not of country of manufacturer / origin) 2.Bidder name is not mentioned as importer on submitted sample, Establishment license no and enlistment , certificate no.not mentioned on submitted sample 3.Attached ISO 13485 could not verified online 4.Registration of Foreign Manufacturer with Regulatory Authority of the Country of Manufacturer for the Quoted Product not attached 5. Attached Enlistment Certificate is not on the name of bidder 6.Attached Quality		

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Sr. No.	Inq.	Generic Name	Bidder / Importer / Sole Agent	Quoted Brand	Manufactured by	Final Status (Responsive/ Non-Responsive)	Reason(s) for Rejection	Grievance of the firm	Remarks
							Compliance Standards (JpMHLW/ CE MDD/MDR/ US FDA 510 K/ Prequalified by WHO (Certificate) of Quoted Item is expired and could not be verified online. 7.Undertaking/Any document not attached regarding Required Storage Temperature as per Product's Requirement 8. Goods Declaration Certificates of Quoted Items Along with all Relevant Documents such as Bill of Lading / Airway Bill, Commercial Invoice and Packing List not attached 9.Attached free sale certificate is not valid (Not notarized/ apostille certification not attached		

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Sr. No.	Inq.	Generic Name	Bidder / Importer / Sole Agent	Quoted Brand	Manufactured by	Final Status (Responsive/ Non-Responsive)	Reason(s) for Rejection	Grievance of the firm	Remarks
7	3	**AV Set Blood Tubing Lining**	Hoora Pharma (Pvt.) Ltd	Nipro Extracorporeal Blood Circuit/china	Ningbo Tiyani Medical Appliances Co-Ltd, China	**Non-Responsive**	1.Valid Notarized Sole Agency Agreement for the Quoted Item not attached 2. Establishment license no. mentioned on submitted sample is not as per attached establishment certificate and enlistment certificate no. mentioned on submitted sample is not as per attached enlistment certificate. 3.Registration of Foreign Manufacturer with Regulatory Authority of the Country of Manufacturer for the Quoted Product not attached 4.Attached Enlistment Certificate is not on the name of bidder 5.6.Attached Quality Compliance Standards (JpMHLW/ CE MDD/MDR/ US FDA 510 K/ Prequalified by WHO (Certificate)		1. The Firm did not provide Valid Notarized Sole Agency Agreement for the Quoted Item. The grievance of the firm was not accepted to the extent of this parameter. 2. Establishment license no. mentioned on submitted sample is not as per attached establishment certificate and enlistment certificate no. mentioned on submitted sample is not as per attached enlistment certificate. The grievance of the firm was not accepted to the extent of this parameter. 3. The firm did not provide Registration of Foreign Manufacturer with Regulatory Authority of the Country of Manufacturer for the Quoted Product. The grievance of the firm was not accepted to the extent of this parameter. 4. The attached Enlistment Certificate is not on the name of bidder. The grievance of the firm was not accepted to the extent of this parameter. 5. The attached Quality Compliance Standards (JpMHLW/ CE MDD/MDR/ US FDA 510 K/ Prequalified by WHO (Certificate) of Quoted Item is expired and could not be verified online. The grievance of the firm was not accepted to the extent of this parameter. 6. The firm did not provide undertaking/Any document regarding Required Storage Temperature as per Product's Requirement. The grievance of the firm was not accepted to the extent of this parameter. 7. The firm did not provide Goods Declaration Certificates of Quoted Items Along with all Relevant Documents such as

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Sr. No.	Inq.	Generic Name	Bidder / Importer / Sole Agent	Quoted Brand	Manufactured by	Final Status (Responsive/ Non-Responsive)	Reason(s) for Rejection	Grievance of the firm	Remarks
							of Quoted Item is expired and could not be verified online. 6..Undertaking/Any document not attached regarding Required Storage Temperature as per Product's Requirement 7.Goods Declaration Certificates of Quoted Items Along with all Relevant Documents such as Bill of Lading / Airway Bill, Commercial Invoice and Packing List not attached 8.Attached free sale certificate is not valid (Not notarized/ apostille certification not attached)		Bill of Lading / Airway Bill, Commercial Invoice and Packing List. The grievance of the firm was not accepted to the extent of this parameter. 8. The firm did not provide valid free sale certificate (Not notarized/ apostille certification not attached). The grievance of the firm was not accepted to the extent of this parameter. Hence the Status of the quoted item remained **"Non -Responsive"**

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Sr. No.	Inq.	Generic Name	Bidder / Importer / Sole Agent	Quoted Brand	Manufactured by	Final Status (Responsive/ Non-Responsive)	Reason(s) for Rejection	Grievance of the firm	Remarks
8	**1**	**AVF Needle 16G (Pairs)**	Bain Medical Private Limited	VITAL/malaysia	VITAL HEALTHCARE SDN. BHD. MALAYSIA	**Non-Responsive**	1.On attached Sole agency agreement the address of manufacturer is not as per attached Enlistment certificate, and .Bidder is mentioned as an agent not as sole agent 2.On Attached ISO 13485 addressof manufacturer is not as Enlistment Certificate 3.Registration of Foreign Manufacturer with Regulatory Authority of the Country of Manufacturer for the Quoted Product not attached. 4.On attached Quality Compliance Standards (JpMHLW/ CE MDD/MDR/ US FDA 510 K/ Prequalified by WHO (Certificate) of Quoted Item the address of manufacturer is not as per enlistment certificate 5. Undertaking/Any	**Grievance of M/s Hoora Pharma against Bain Medical Private Limited:** Please verify the Registration of Foreign Manufacturer with Regulatory Authority of the Country of Manufacturer for the Quoted Product. Please verify quoted Brand name in FSC and other quality certificates.	The Firm did not contest for the quoted item **Grievance of M/s Hoora Pharma against Bain Medical Private Limited:** Mr M. Ahmed attended the meeting on the behalf of M/s Hoora Pharma but no one attended the meeting on the behalf of M/s Bain Medical Private Limited. The committee heard the viewpoints of both firms. The M/s Bain Medical Private Limited is aleady non-responsive in its own grievance. Hence, the GRC upheld the decision of the technical evaluation committee and status remained Non-Responsive. Hence, the status of quoted item remained **Non-responsive.**

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							document not attached regarding Required Storage Temperature as per Product's Requirement 6..On attached GD, Bill of ladding , Commercial Invoice and Packing list manufacturer name is not as per enlistment Certificate 7..Manufacturer address is not as per enlistment,certificate, Quoted brand freely available in the country of origin not mentioned and Not notarized by Country of manufacturer/ origin on attached free sale certificate.		