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MINUTES OF MEETING OF THE GRIEVANCE REDRESSAL COMMITTEE HELD ON 03th DECEMBER, 2020 AT 11:00 A.M TO REDRESS THE GRIEVANCE APPLICATIONS OF THE FIRMS AGAINST EVALUATION REPORT FOR THE PREQUALIFICATION OF PHARMACEUTICAL MANUFACTURING UNITS AND SOLE AGENTS OF FOREIGN PRINCIPLES OF MEDICAL DEVICES FOR THE FY 2020-21

A meeting of the Grievance Redressal Committee was held on 03-12-2020 at 11:00 A.M in committee room of Directorate General Health Services, Punjab, to address the grievances of the applicants, as per Rule 67 of Punjab Procurement Rules, 2014 (Amended), for the Prequalification of Pharmaceutical Manufacturing Units and Sole Agents of Foreign Principles of Medical Devices for the FY 2020-21.
Following members of Grievance Redressal Committee attended the meeting:

Sr. No.	Participants	
1.	Director Health Services (CD&EPC), DGHS	**Chairman/Convener**
2.	Program Director, IRMNCH&NP	**Member**
3.	Program Manager, Hepatitis Prevention & Infection Control Program, DGHS	**Member**
4.	Director Pharmacy/Secretary Purchase Cell, DGHS	**Member**
5.	Senior Law Officer (Litigation Cell), DGHS	**Member**

Following member(s) of the PQ Evaluation Committee presented the cases on behalf of the PQ Evaluation Committee:

Sr. No.	Member(s)
1.	Prequalification Specialist (Medicine), P&SHD
2.	Tender Coordination Officer (Medicine), P&SHD
3.	Deputy Director Pharmacy, DGHS

The Chair welcomed all the participants and briefed about agenda of meeting i.e. Grievance Redressal of firms against Evaluation Report for the Prequalification of Pharmaceutical Manufacturing Units and Sole Agents of Foreign Principles of Medical Devices for the FY 2020-21.

The Chair instructed the representatives of aggrieved firms to come one by one serial wise based on receipt of grievance so that proper hearing/ redressal of grievance may be ensured. The grievances of firms and decisions of grievance redressal committee are as follow:

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Akram Brothers & Co.	49	Poly propylene Size 1, 40mm 1/2 circle RB Needle	Not Qualified Financial Turnover as well as bank statement verification required	Minimum financial turnover is less than Rs.300 Million, Bank statement of 2019-20 is not attached.	Not Prequalified		Sir, We M/S Akram Brothers & Co., with reference to the Pre-qualification Evaluation Report of Manufacturing Units & Sole Agents of Foreign Principals for Medical Devices 2020-21 for DGHS P&SHD would like to state that the reason for our firm's non pre-qualification is given that the minimum turnover is less than 300 million and that the bank statement is not attached. But according to the tax return for the financial year 2019-2020 the turnover is more than 300 million rupees that is 300.42 million rupees. The tax return is already provided online as well as in the hard copy. The firm is also providing the bank statement for the year 2019-20 for the purpose of verification. Kindly consider this and find attached tax return for year 2019-20 and the Bank statement for the year 2019-20.	Mr. Naveed Shaukat, Manager, from M/s Akram Brothers & Co. attended the meeting and presented their grievance to the grievance redressal committee. The committee heard the view point of the representative of the firm which was examined in the light of Evaluation Report. The committee after due deliberation and discussion, keeping in view the evaluation criteria decided that: The firm provided verified bank statements of FY 2019-20 of Firm's Title account, which were **accepted**. Hence, the grievance of the firm was accepted and status of the firm declared "**Prequalified**" for all quoted items **except** Catgut Chromic: Size 1, with 40mm Intestinal RB Needle, Size 1,30mm,½ Circle RB Needle, Size 1,40mm,curved Needle, Size2/0 ,30mm, 1/2 Circle Round Body needle as the quoted items did not comply with Quality Compliance Standards (EMA/JMHLW/US FDA/prequalified by WHO).
Akram Brothers & Co.	50	Poly propylene ,Size 2/0, 30mm 1/2 circle RB Needle	Not Qualified Financial Turnover as well as bank statement verification required	Minimum financial turnover is less than Rs.300 Million, Bank statement of 2019-20 is not attached.	Not Prequalified			
Akram Brothers & Co.	51	Poly propylene ,Size 2/0,60mm Straight Cutting needle (SCN)	Not Qualified Financial Turnover as well as bank statement verification required	Minimum financial turnover is less than Rs.300 Million, Bank statement of 2019-20 is not attached.	Not Prequalified			
Akram Brothers & Co.	11	Black Silk,Size1 ,40mm 3/8 Circle curve cutting (CC) needle	Not Qualified Financial Turnover as well as bank statement verification required	Minimum financial turnover is less than Rs.300 Million, Bank statement of 2019-20 is not attached.	Not Prequalified			
Akram Brothers & Co.	16	Catgut Chromic, Size 1, with 40mm Intestinal RB Needle	Not Qualified Financial Turnover as well as bank statement verification required	Minimum financial turnover is less than Rs.300 Million, Bank statement of 2019-20 is not attached.	Not Prequalified	The quoted item did not comply with Quality Compliance Standards (EMA/JMHLW/US FDA/prequalified by WHO)		
Akram Brothers & Co.	52	Polyglactin/ Polyglycolic acid, Size 1,40mm.1/2 Circle Round Body needle	Not Qualified Financial Turnover as well as bank statement verification required	Minimum financial turnover is less than Rs.300 Million, Bank statement of 2019-20 is not attached.	Not Prequalified			
Akram Brothers & Co.	53	Polyglactin/ Polyglycolic acid,size 2/0,30mm, 1/2 Circle Round Body needle	Not Qualified Financial Turnover as well as bank statement verification required	Minimum financial turnover is less than Rs.300 Million, Bank statement of 2019-20 is not attached.	Not Prequalified			

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Akram Brothers & Co.	17	Catgut Chromic, Size 1,30mm, ½ Circle RB Needle	Not Qualified Financial Turnover as well as bank statement verification required	Minimum financial turnover is less than Rs.300 Million, Bank statement of 2019-20 is not attached.	Not Prequalified	The quoted item did not comply with Quality Compliance Standards (EMA/JMHLW/US FDA/prequalified by WHO)		
Akram Brothers & Co.	18	Catgut Chromic, Size 1,40mm,curved Needle	Not Qualified Financial Turnover as well as bank statement verification required	Minimum financial turnover is less than Rs.300 Million, Bank statement of 2019-20 is not attached.	Not Prequalified	The quoted item did not comply with Quality Compliance Standards (EMA/JMHLW/US FDA/prequalified by WHO)		
Akram Brothers & Co.	19	Catgut Chromic, Size2/0 ,30mm, 1/2 Circle Round Body needle	Not Qualified Financial Turnover as well as bank statement verification required	Minimum financial turnover is less than Rs.300 Million, Bank statement of 2019-20 is not attached.	Not Prequalified	The quoted item did not comply with Quality Compliance Standards (EMA/JMHLW/US FDA/prequalified by WHO)		
Akram Brothers & Co.	9	Black Silk,2/0,30mm 1/2 circle roud body needle	Not Qualified Financial Turnover as well as bank statement verification required	Minimum financial turnover is less than Rs.300 Million, Bank statement of 2019-20 is not attached.	Not Prequalified			
Akram Brothers & Co.	10	Black Silk,Size1 , 30mm, 1/2Circle round body needle	Not Qualified Financial Turnover as well as bank statement verification required	Minimum financial turnover is less than Rs.300 Million, Bank statement of 2019-20 is not attached.	Not Prequalified			
Akram Brothers & Co.	8	Black Silk ,Size 2/0,60mm straight cutting needle	Not Qualified Financial Turnover as well as bank statement verification required	Minimum financial turnover is less than Rs.300 Million, Bank statement of 2019-20 is not attached.	Not Prequalified			

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Al-Hamd Enterprises	37	Foley's catheter (all sizes) Sterile Packs All sizes	Qualified		Not Prequalified	Valid DRC/ Device Enlistment certificate not attached	Kindly find the attached file of Grievance Application with required documents of Medical Device and Surgical Dressing for your kind perusal Thank you!	Mr. Javed Iqbal, Institutional Manager, from M/s Al-Hamd Enterprises attended the meeting and presented their grievance to the grievance redressal committee. The committee heard the view point of the representative of the firm which was examined in the light of Evaluation Report. The committee after due deliberation and discussion, keeping in view the evaluation criteria decided that: 1. The firm do not have enlistment of Foley's catheter from DRAP. Though the firm has applied for the enlistment of the quoted product, yet it has not been registered previously from DRAP. Hence the grievance of the firm for this item was **rejected** and the decision of PQ evaluation committee was upheld as "**Not Prequalified**". 2. The firm provided enlistment certificate for Sterile Surgical Gloves with manufacturer registered by the name "Suzhou Colour-way Enterprise Development Co., Ltd.". Whereas the name of manufacturer is "Suzhou Colour-way New Material Co., Ltd.", which was not accepted. Moreover, the firm provided application to DRAP for the change of manufacturer but it did not specify what name to be changed with which. Hence the grievance of the firm for this item was **rejected** and the decision of PQ evaluation committee was upheld as "**Not Prequalified**". Hence status of the firm declared "**Prequalified**" for all quoted items **except** Foley's catheter & Sterile Surgical Gloves.
Al-Hamd Enterprises	56	Sterile Surgical Gloves Pairs 6 ½, 7, 7 ½ (Powdered)	Not Qualified	Name of Principle is different in documents	Not Prequalified	Name of Principle is different in documents		
Al-Hamd Enterprises	39	I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 18G	Qualified		Prequalified			
Al-Hamd Enterprises	42	I.V Cannula with/without Injection Port with Integrated Closing Cone Sterile Pack 24G	Qualified		Prequalified			
Al-Hamd Enterprises	41	I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 22G	Qualified		Prequalified			
Al-Hamd Enterprises	40	I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 20G	Qualified		Prequalified			

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Ali Gohar & Company (Private) Limitted	55	Spinal Needle Sterile Packs All Sizes	Not Qualified	Date of issuance of Sole Agency Agreement is less than one year till the date of submission of PQD; Expired ISO 13485 Certificate; Minimum financial turnover is less than Rs.300 Million, tax return record not attached; Valid registration of manufacturing firm with the chamber of commerce from country of manufacture not attached; Undertaking of "none of its	Not Prequalified	Date of issuance of Sole Agency Agreement is less than one year till the date of submission of PQD; Quoted product is not tried and tested in local environment for at least three years Copies of Goods; Declaration certificates of quoted items of last three years not attached	Sir, Reference to the Dis-qualification of our submitted product, (Spinal Needle of All Sizes). We hereby confirm that we have all the concerned documents as mentioned in the evaluation that have not provided. We are submitting the copy of said documents (followings of Sr.# 22 Inq. No. 55) for the purposes of evaluation please. Firm wise required documents. • Date of issuance of Sole Agency Agreement is less than one year till the date of submission of PQD (Copy is attached) • Expired ISO 13485 Certificate. (Copy is attached) • Minimum financial turnover is less than Rs.300 Million, tax return record not attached. (Copy is attached) • Valid registration of manufacturing firm with the chamber of commerce from country of manufacture not attached. (Copy is attached) • Undertaking of none of its manufactured batch sample has been declared Spurious/Adulterated since 2017 onward. (Copy is attached) • Any Conviction by Drug Court against firm, the applicant accepts all the terms and Conditions of the Prequalification Documents" not attached. (Copy is attached) Item wise required documents. • Date of issuance of Sole Agency Agreement is less than one year till the date of submission of PQD. (Copy is attached) • Quoted product is not tried and tested in local environment for at least three years, Copies of Goods. (Copy is attached) • Declaration certificates of quoted items of last three years not attached. (Copy is attached) Hope, you would kindly consider our request favorably and let us serve to you in future. Thanking you & assuring you of our beast services and cooperation at all the times, we remain with best regards.	Mr. Naseer Ahmed, Product Manager, from M/s Ali Gohar & Co. (Pvt.) Ltd. attended the meeting and presented their grievance to the grievance redressal committee. The committee heard the view point of the representative of the firm which was examined in the light of Evaluation Report. The committee after due deliberation and discussion, keeping in view the evaluation criteria decided that: 1. The firm submitted valid Sole Agency agreement of the principle Smiths Medical International, UK, which was **accepted**. 2. The firm submitted valid ISO 13485 certificate of the principle Smiths Medical International, UK, which was **accepted**. 3. The firm submitted FBR Sales Tax Return of FY 2019 as substantial evidence for annual turnover more that Rs.300 Million, which was **accepted**. 4. The firm provided copies of Purchase Orders Goods Declaration certificates of quoted item of last 3 years consecutively, which were **accepted**. 5. The firm provided undertaking of "none of its manufactured batch sample has been declared Spurious/Adulterated since 2017 onward", "Any Conviction by Drug Court against firm", which were **accepted**. Hence, the grievance of the firm was **accepted** and the status of the firm declared as "**Prequalified**".
Anwar & Sons	10	Black Silk,Size1 , 30mm, 1/2Circle round body needle	Not Qualified	PQD Application Not submitted	Not Prequalified	PQD Application Not submitted	Sir, This refers to above mentioned report and as per this report we declared "Not Prequalified "for the reason" PDQ application not submitted" inquiry number 10,51,52,53,9,49 & 50 We would like to draw your kind attention on our letter # As-Accts/2020-21/000903 dated 28-10-2020, we explained the circumstances of delay by some hour and requested to allow us the submission of hard copy of the PQD application since on line submission was within the stipulated period. As we explained in our above referred letter the circumstances were beyond our control (acknowledged copy of the letter attached) We M/s Anwar & Sons of Rawalpindi remained prequalified supplier for the last many years and served the hospitals with our quality and cost-effective products. Keeping in view our past history of regular prequalified supplier, you will give due consideration to our request and allow us to submit hard copy of PQD Application to supplement the deficiency. Please See The Attachment For Further Details	Mr. Khurram Shahzad, ASM, from M/s Anwar & Sons attended the meeting and presented their grievance to the grievance redressal committee. The committee heard the view point of the representative of the firm which was examined in the light of Evaluation Report. The committee after due deliberation and discussion, keeping in view the ITA of PQ Document, it was decided that: The firm did not submit hard copy of the PQ Application within closing date and time which is mandatory as per PPR 2014. Hence grievance of the firm was **rejected** and status of the firm remained "**Not Prequalified**"**.**
Anwar & Sons	51	Poly propylene ,Size 2/0,60mm Straight Cutting needle (SCN)	Not Qualified	PQD Application Not submitted	Not Prequalified	PQD Application Not submitted		
Anwar & Sons	52	Polyglactin/ Polyglycolic acid, Size 1,40mm.1/2 Circle Round Body needle	Not Qualified	PQD Application Not submitted	Not Prequalified	PQD Application Not submitted		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Anwar & Sons	53	Polyglactin/ Polyglycolic acid,size 2/0,30mm, 1/2 Circle Round Body needle	Not Qualified	PQD Application Not submitted	Not Prequalified	PQD Application Not submitted		
Anwar & Sons	9	Black Silk,2/0,30mm 1/2 circle roud body needle	Not Qualified	PQD Application Not submitted	Not Prequalified	PQD Application Not submitted		
Anwar & Sons	49	Poly propylene Size 1, 40mm 1/2 circle RB Needle	Not Qualified	PQD Application Not submitted	Not Prequalified	PQD Application Not submitted		
Anwar & Sons	50	Poly propylene ,Size 2/0, 30mm 1/2 circle RB Needle	Not Qualified	PQD Application Not submitted	Not Prequalified	PQD Application Not submitted		
ASTO Life Sciences Private Limited	25	Disposable syringe 10ml with needle. (Blister pack)	Qualified		Prequalified		Sir, To, 23rd of November, 2020 Director General (DG), Directorate General Health Services (DGHS), Punjab, 24- Cooper Road, Lahore. Subject: GRIEVANCE IN RESPONSE TO THE PRE-QUALIFICATION EVALUATION REPORT FOR MANUFACTURING UNIT AND SOLE AGENTS OF FOREIGN PRINCIPLES FOR MEDICAL DEVICES 2020-2021 FOR DGHS, PRIMARY & SECONDARY HEALTHCARE DEPARTMENT Respected Sir, With reference to the Pre-Qualification Evaluation Report for manufacturing unit and sole agents of foreign principles for medical devices 2020-2021 for DGHS, Primary & Secondary Healthcare (P&SH) Department uploaded on your official website on 13.11.2020. Our firm, ASTO Life Sciences Pvt Ltd was not prequalified on below mentioned grounds: 1. Quoted product is not tried and tested in local environment for at least three years (2019); Copies of Goods Declaration certificates of quoted items of last three years not attached (2019). We have grievance on this point that ASTO Life Sciences Pvt Ltd is sole / authorized agent for Becton Dickinson (BD), who is globally accepted and reputed leader in making world class medical devices having multiple of certifications around the globe. Subject criteria regarding the consecutive 03-year local market experience is not relevant to define or evaluate the quality of any item. Meanwhile, the same item was pre-qualified in 2017-18 by Primary & Secondary Healthcare Department and we provided around 40 million syringes to your good department across the Punjab smoothly. 2. As per evaluation report, testing report of any WHO accredited laboratory for (AD)/(RUP) syringes not attached. We are also submitting grievance on this point that; we are attaching Good Laboratory Practice (GLP) report of our items which indicates that our item meets all the bio-compatibility compliance. (May be seen at Annex-A). 3. In this connection, as per Punjab Procurement Regulatory Authority (PPRA), Government of The Punjab notification, the procuring agency while the prequalification process has to prequalify at least 03 bidders for further bidding process and in case, when one bidder prequalified then the procuring agency should reconsider the prequalification criteria to attract more bidders. Hopefully, your kind attention and consideration on above mentioned details will be helpful for the acceptance of our grievance. Thanking you for your anticipation. Yours truly, For ASTO Life Sciences Private Limited	Mr. Ahsan Mushtaq, Financial Controller, from M/s ASTO Life Sciences (Pvt.) Ltd. attended the meeting and presented their grievance to the grievance redressal committee. The committee heard the view point of the representative of the firm which was examined in the light of Evaluation Report. The committee after due deliberation and discussion, keeping in view the evaluation criteria decided that: 1. The firm provided WHO Performance Quality Safety certificates of the quoted items “Emerald TM PRO” 2ml, 5ml & 10ml as substantial evidence for Testing report of any WHO accredited laboratory for (AD)/(RUP) syringes which were **accepted**. 2. The firm did not provide and the requisite copies of GDs and POs of last three years consecutively. Hence, the grievance of the firm was rejected and the decision of PQ evaluation committee was upheld as “**Not Prequalified**” **expect** Disposable syringe 3ml, 5ml and 10ml with needle.
ASTO Life Sciences Private Limited	28	Disposable Syringe 3ml with needle. (Blister pack)	Qualified		Prequalified			

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
ASTO Life Sciences Private Limited	30	Disposable syringe 5ml with needle. (Blister pack)	Qualified		Prequalified			
ASTO Life Sciences Private Limited	55	Spinal Needle Sterile Packs All Sizes	Qualified		Not Prequalified	Quoted product is not tried and tested in local environment for at least three years Copies of Goods (2017); Declaration certificates of quoted items of last three years not attached (2017)		
ASTO Life Sciences Private Limited	3	Auto Disable (AD)/re-use prevention (RUP) Syringe 2/3ml with needle (Blister Pack)	Qualified		Not Prequalified	Quoted product is not tried and tested in local environment for at least three years (2019); Copies of Goods Declaration certificates of quoted items of last three years not attached (2019); Testing report of any WHO accredited laboratory for (AD)/(RUP) syringes not attached.		
ASTO Life Sciences Private Limited	4	Auto Disable (AD)/re-use prevention (RUP) Syringe 10ml with needle (Blister Pack)	Qualified		Not Prequalified	Quoted product is not tried and tested in local environment for at least three years (2018, 2019); Copies of Goods Declaration certificates of quoted items of last three years not attached (2017, 2018, 2019);		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
ASTO Life Sciences Private Limited	5	Auto Disable (AD)/re-use prevention (RUP) Syringe 5ml with needle (Blister Pack)	Qualified		Not Prequalified	Quoted product is not tried and tested in local environment for at least three years (2019); Copies of Goods Declaration certificates of quoted items of last three years not attached (2019); Copies of Goods Declaration certificates of quoted items of last three years not attached (2019); Testing report of any WHO accredited laboratory for (AD)/(RUP) syringes not attached.		
Atco Laboratories Limited	60	Surface Disinfectant Solution Of appropriate composition	Not Qualified	No separate undertakings of clause 19, 17 and 9 are available. clause 8. The firm has not provided/attached the product's valid CE/UNFPA/JMHLW/US FDA approval certification or prequalification by WHO. ISO certificate 13485 was not provided	Not Prequalified	clause1. Quality Compliance Standards (CE/JMHLW/US FDA or prequalified by WHO (Certificate) is not provided.	With reference to your evaluation report of the above mentioned reference prequalification. It is to bring in your kind knowledge that below mentioned are the justifications and replies to your objections. A. Firm Wise 1. No separate undertakings of clause 19, 17 and 9 are available. a. We have submitted undertaking(s) for the above mentioned clauses. Resubmitting submitting separate undertakings for your kind perusal. 2. Clause 8. The firm has not provided/attached the product's valid CE /UNFPA /JMHLW /US FDA approval certification or prequalification by WHO. a. Our Quoted Items HiClean Advance & HiClean Instrument are locally manufactured in a DRAP approved facility & also approved by DRAP as disinfectant products (DRAP registration is already submitted). The ingredients are as per WHO & CDC Guidelines. UNFPA/JMHLW/US FDA & Prequalification by WHO is not applicable on these products. 3. ISO certificate not provided. a. We have already submitted following ISO certificates. Copies of the same is also enclosed with this letter. i. ISO 9001:2015. ii. ISO 45001:2018 iii. ISO 14001:2015 In the light of the above points, we request you to kindly accept our prequalification application for these products.	Mr. Muneer Iqbal from ATCO Laboratories Limited attended the meeting and presented their grievance to the grievance redressal committee. The committee heard the view point of the representative of the firm which was examined in the light of Evaluation Report. The committee after due deliberation and discussion, keeping in view the required parameters in detail, decided that: **1)** The firm provided undertakings of **clause 19, 17 and 9** which were **accepted**. **2)** The firm did not provide ISO 13485. **3)** The firm did not provide/attach the product's valid CE/UNFPA/JMHLW/US FDA approval certification or prequalification by WHO.Certificates. **4)** The firm did not provide item wise clause1. Quality Compliance Standards (CE/JMHLW/USFDA or prequalified by WHO (Certificate). **5)** The firm did not provide purchase order of three consecutive years for Instrumental Disinfectant Solution Of appropriate composition which was not accepted. Hence, the firm was "**Not Prequalified".**
Atco Laboratories Limited	44	Instrumental Disinfectant Solution Of appropriate composition	Not Qualified	No separate undertakings of clause 19, 17 and 9 are available. clause 8. The firm has not provided/attached the product's valid CE/UNFPA/JMHLW/US FDA approval certification or prequalification by WHO. ISO certificate not provided	Not Prequalified	1) clause1. Quality Compliance Standards (CE/JMHLW/US FDA or prequalified by WHO (Certificate) is not provided. 2) clause 5. purchase order of only 2017 is provided		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Coral Pharmaceuticals	49	Poly propylene Size 1, 40mm 1/2 circle RB Needle	Not Qualified	The annual turnover of the firm is less than 300 Million rupees.	Not Prequalified	No undertaking on stamp paper for clause no. 8,9 & 10. GD certificate for year 2018 & 2019 is not provided. POs of the quoted item for the relevant 3 years are not provided.	Sir, We have applied & submitted all documents for Pre-Qualification for the year 2020-21. Further enclosed herewith documents as required. You are requested to please accept our documents in Grievance Committed meeting & oblige.	Mr. Laeeq Ahmad Business Development Manager from M/s Coral Pharmaceuticals attended the meeting and presented their grievance to the grievance redressal committee. The committee heard the viewpoint of the firm which was examined in the light of Evaluation Report. The committee after due deliberation and discussion, keeping in view the required parameters in detail decided that: 1. The firm's annual financial turnover was less than Rs. 300 million rupees against the firm wise knockdown criteria clause no. 11. Hence grievance of the firm was **rejected** to this parameter. 2. The firm provided undertakings on legalized/notarized stamp paper against the item wise knockdown criteria clause no. 8, 9 & 10 which was **accepted**. 3. The firm did not provide GDs and POs for relevant three years for all its quoted items **except** the quoted items Dysilk 2/0 and Dysilk 1/0. Hence grievance of the firm was **rejected**, and status of all quoted items remained as **"Not Prequalified"**.
Coral Pharmaceuticals	9	Black Silk,2/0,30mm 1/2 circle roud body needle	Not Qualified	The annual turnover of the firm is less than 300 Million rupees.	Not Prequalified	No undertaking on stamp paper for clause no. 8,9 & 10. GD certificate for year 2018 & 2019 is not provided. POs for the quoted item for relevant 3 years are not provided.		
Coral Pharmaceuticals	17	Catgut Chromic, Size 1,30mm, ½ Circle RB Needle	Not Qualified	The annual turnover of the firm is less than 300 Million rupees.	Not Prequalified	No undertaking on stamp paper for clause no. 8,9 & 10. GD certificate for year 2018 & 2019 is not provided. POs of the quoted item for the relevant 3 years are not provided.		
Coral Pharmaceuticals	16	Catgut Chromic, Size 1, with 40mm Intestinal RB Needle	Not Qualified	The annual turnover of the firm is less than 300 Million rupees.	Not Prequalified	No undertaking on stamp paper for clause no. 8,9 & 10. GD certificate for year 2018 & 2019 is not provided. POs of the quoted item for the relevant 3 years are not provided.		
Coral Pharmaceuticals	19	Catgut Chromic, Size2/0 ,30mm, 1/2 Circle Round Body needle	Not Qualified	The annual turnover of the firm is less than 300 Million rupees.	Not Prequalified	No undertaking on stamp paper for clause no. 8,9 & 10. GD certificate for year 2018 & 2019 is not provided. POs of the quoted item for the relevant 3 years are not provided.		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Coral Pharmaceuticals	53	Polyglactin/ Polyglycolic acid,size 2/0,30mm, 1/2 Circle Round Body needle	Not Qualified	The annual turnover of the firm is less than 300 Million rupees.	Not Prequalified	No undertaking on stamp paper for clause no. 8,9 & 10. GD certificate for year 2018 & 2019 is not provided. POs of the quoted item for the relevant 3 years are not provided.		
Coral Pharmaceuticals	52	Polyglactin/ Polyglycolic acid, Size 1,40mm.1/2 Circle Round Body needle	Not Qualified	The annual turnover of the firm is less than 300 Million rupees.	Not Prequalified	No undertaking on stamp paper for clause no. 8,9 & 10. GD certificate for year 2018 & 2019 is not provided. POs of the quoted item for the relevant 3 years are not provided.		
Coral Pharmaceuticals	50	Poly propylene ,Size 2/0, 30mm 1/2 circle RB Needle	Not Qualified	The annual turnover of the firm is less than 300 Million rupees.	Not Prequalified	No undertaking on stamp paper for clause no. 8,9 & 10. GD certificate for year 2018 & 2019 is not provided. POs of the quoted item for the relevant 3 years are not provided.		
Coral Pharmaceuticals	51	Poly propylene ,Size 2/0,60mm Straight Cutting needle (SCN)	Not Qualified	The annual turnover of the firm is less than 300 Million rupees.	Not Prequalified	No undertaking on stamp paper for clause no. 8,9 & 10. GD certificate for year 2018 & 2019 is not provided. POs of the quoted item for the relevant 3 years are not provided.		
Coral Pharmaceuticals	10	Black Silk,Size1, 30mm, 1/2Circle round body needle	Not Qualified	The annual turnover of the firm is less than 300 Million rupees.	Not Prequalified	No undertaking on stamp paper for clause no. 8,9 & 10. GD certificate for year 2018 &2019 is not provided. POs for the quoted item for relevant 3 years are not provided.		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
DKT Pakistan Private Limited	46	Male Latex Condom (UNFPA/ WHO prequalifi ed)	Not Qualified	The financial turnover is less than 300 Million rupees. Relevant undertakings on stamp paper are neither legalized nor notarized.	Not Prequalified	No DRC, GD certificates and POs of the quoted item for relevant 3 years have been provided. No undertakings for the quoted item on legalized and notarized stamp paper have been provided.	Sir, November 20, 2020. The Chairman / Convener, Grievance Redressal Committee, Director General Health Services, Punjab, Lahore. GRIEVANCE APPLICATION FOR PRE-QUALIFICATION Sir, We write this letter to express our grievance against the decision of the Technical Evaluation Committee, wherein, our firm has not been qualified on the basis of reasons, i.e. (1) the financial turnover is less than 300 Million rupees, (2) relevant undertakings on stamp paper are neither legalized nor notarized, (3) No DRC, GD certificates and POs of the quoted item for relevant 3 years have been provided and (4) No undertakings for the quoted item on legalized and notarized stamp paper have been provided. We have removed all the reasons and documentation / information as detailed below is being attached:- Item No. Generic Name Brand Name Manufactured by Rectification 45 IUCD (CU-T 380A) UNFPA/WHO Prequalified Pro Green Injeflex Industria e Comercio De 1- Our financial turnover is more than 821 Million rupees (copy of Annual Sales Tax Return the years, 2017-18, 2018-19 and 2019-20 & Bank Statements for the years, 2017-18, 2018-19 and 2019-20 attached. 2- Undertakings duly notarized by the Notary Public Attached. 3- Copy of Form-8A [see rule 15(5)] Certificate of Enlistment or Registration of a Medical Device or Accessory or Component Import along with Annexures is attached. 4- Copy of Goods Declaration. GD-1 attached. 5- Copies of Purchase Orders attached. 6- Undertakings duly notarized by the Notary Public Attached. - Copy of Agency Agreement (dated 20.09.2019, valid for a period of 60 months) attached. - UNFPA Prequalified TCu380A IUD Manufacturers (at Sr. No. 3) attached. 46 Male Latex Condom (UNFPA/WHO prequalified) JOSH Thai Nippon Rubber Industry Public Limited 1- Our financial turnover is more than 821 Million rupees (copy of Annual Sales Tax Return the years, 2017-18, 2018-19 and 2019-20 & Bank Statements for the years, 2017-18, 2018-19 and 2019-20 attached. 2- Undertakings duly notarized by the Notary Public Attached. 3- Copy of request, dated 11.07.2020 for registration + paid Challan of the quoted item attached. 4- Copy of Goods Declaration. GD-1 attached. 5- Copies of Purchase Orders attached. 6- Undertakings duly notarized by the Notary Public Attached. - Copy of Authorization Letter, dated 18.07.2019 valid for 5 years attached. - UNFPA Prequalified Male Condom Manufacturing Sites (at Sr. No. 18) attached. In the light of explained circumstances, it is requested to please review the decision of Technical Evaluation Committee and qualify our quoted items for healthy competition and in the best interest of the general public. Thanks. Yours faithfully, DKT Pakistan Private Limited.	Mr. Jalal Akhtar Distributor from M/s DKT Pakistan attended the meeting and presented their grievance to the grievance redressal committee. The committee heard the viewpoint of the firm which was examined in the light of Evaluation Report. The committee after due deliberation and discussion, keeping in view the required parameters in detail decided that: 1. The firm submitted FBR document and bank statement of its title account to substantiate its claim of its annual turnover was more than 300 million rupees which was **accepted**. Hence grievance of the firm was accepted to the extent of this parameter. 2. The firm provided relevant undertakings on the legalized/notarized stamp paper against the firm wise and item wise knockdown criteria of prequalification document which was also **accepted**. 3. The firm provided valid DRC for the quoted item Pro Green which was also **accepted** but failed to provide GD certificates and POs for consecutive three years for this quoted item. Hence grievance of the firm was **rejected**, and status of the quoted item Pro Green remained as **"Not Prequalified"**. 4. The firm did not provide valid DRC, GD certificates and POs for consecutive three years for quoted item JOSH. Hence grievance of the firm was **rejected**, and status of the quoted item JOSH remained as **"Not Prequalified"**.
DKT Pakistan Private Limited	45	IUCD (CU-T 380A) UNFPA/ WHO Prequalifi ed	Not Qualified	The financial turnover is less than 300 Million rupees. Relevant undertakings on stamp paper are neither legalized nor notarized.	Not Prequalified	No DRC, GD certificates and POs of the quoted item for relevant 3 years have been provided. No undertakings for the quoted item on notarized or legalized stamp paper have been provided.		
Fresenius Medical Care Pakistan (Pvt.) Ltd	6	AV Fistula Needles (Arterial+ venous) with fixed wings. (Individual ly Sterile Packed) size 16/17G.	Not Qualified	CE certificate of NIPRO Thiland (Manufacturer) Not provided	Not Prequalified	clause 1: Quality compliance standard certificates not provided for manufacturing sites in Thailand as mentioned on product enlistment certificate	Sir, With reference to the announcement of technical evaluation report of the Pre-qualification of Medical Devices, we would like to submit the following documents / Certificates against the AVF Needles for your kind consideration. Sr. No. 75 , Inquiry No. 6 Generic Name: AV Fistula Needles (Arterial + Venous) with fixed wings. 16/17G Objections: clause 1: Quality compliance standard certificates not provided for manufacturing sites in Thailand as mentioned on product enlistment certificates. Clarification: "CE holder of Fresenius Medical Care label Nipro needles is Fresenius Medical Care AG & Co KGaA, not Nipro". Fresenius Medical Care AG & Co. KGaA, Germany is legal manufacturer (Product licence holder) and has the responsibility to place the medical devices on the market and is stated on all labelling of the medical devices. Nipro Corporation is a contract manufacturer and manufacturers medical devices on behalf of Fresenius Medical Care AG & Co. KGaA, Germany. Legal Manufacturer: Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg, Germany Contract Manufacturer: Nipro Corporation 3-9-3, Honjo-Nishi, Kita-ku Osaka 531-8510, Japan Production Site: Nipro (Thailand) Corporation Ltd., 10/2 Moo 8 Bangnomko, Sena, Phra Nakhon Si Ayutthaya 131, Thailand All the related documents/certificates [EC Certificate, Declaration of Production site, DRAP registration certificate of Fistula Needles and ISO 13485:2016 quality certificate of manufacturing site] are attached for your review. We have already submitted these documents with our prequalification application. Based on the above points, we request you to re-evaluate our prequalification application and declare us 'prequalified'.	Mr. Mohammad Sohail Manager Regulatory affair from M/S Fresenius Medical Care Pakistan (Pvt.) Ltd attended the meeting and presented their grievance to the grievance redressal committee. The committee heard the view point of the firm which was examined in the light of Evaluation Report. The committee after due deliberation and discussion, keeping in view the required parameters in detail decided that: 1. The Firm submitted CE certification with declaration bearing the manufacturing facility of AVF needle of Nipro Thailand. Furthermore, firm submitted same in Drug regulatory Authority of Pakistan as a mandatory document for Enlistment of medical devices. In addition, firm also submitted valid enlistment certificate issued by Drug Regulatory Authority of Pakistan bearing Manufacturing facility i.e. Nipro Thailand of same. Hence, grievance of the firm was **accepted**. Keeping in view the compliance of the requisite compulsory parameters, the grievances of the firm was accepted and status of the firm is declared as **"Prequalified**".

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Fresenius Medical Care Pakistan (Pvt.) Ltd	38	Hollow Fiber Dialyzer (All Sizes) Individuall y Sterile Packed (with BTL and A.V Fistula Needle Pair)	Qualified		Prequalified			
Fresenius Medical Care Pakistan (Pvt.) Ltd	7	AV Set Blood Tubing Lining (6.3-6.6mm) with one transduce r protector (Fluid Barrier) & Pre-Pump Arterial Pressure Monitorin g Line (Individual ly Sterile Packed).	Qualified		Prequalified			
Hakimsons (Private) Limited	47	Nasogast ric tube (all sizes) Sterile Packs	Not Qualified	Drugs Sale License not provided. FBR income tax return/sales Tax return documents not provided. Clause#19. Affidavit is not stamped by notary public.	Not Prequalified	DRC Not provided. Clause #11. Goods declaration certificate for the year 2018 is not attached.	Sir, with due respect we would like to reapply for our foreign principles who did not get prequalified 1.Ningbo Mflab Medical Instruments Co.,ltd 2. Jiangsu Suyun Medical Materials Co.,ltd, the reason for not prequalifying of both the companies stated, "firm wise reason of rejection is drug sale license not provided, FBR income tax return/sales tax return documents not provided and clause#19 affidavit is not stamped by notary public and item wise reason of rejection is DRC not provided and Goods declaration certificates for the last three years of mentioned products", we are here with attaching copy of drug sale license ,copy of FBR income tax return/sales tax return documents , clause # 19 affidavit stamped by notary public, copy of application for DRC and cash deposit slip of products instead of DRC because we have applied for said products and we are awaited for evaluation of these products then we will get DRC, copy of Goods declaration certificate for the last three years of mentioned products please go through our documents and if any further details are required we are willing to provide as many details needed.	Mr. M. Tariq Afzal ,field manager. from M/s Hakimsons (Pvt) Ltd. attended the meeting and presented their grievance to the grievance redressal committee. The committee heard the viewpoint of the firm which was examined in the light of Evaluation Report. The committee after due deliberation and discussion, keeping in view the required parameters in detail decided that: 1. Firm provided drug sale license (firm wise clause no. 2). Hence, firm grievance was **accepted**. 2. Firm provided FBR Tax returns of FY 2017-18 & 2018-19, which were less than Rs. 300 million. Hence, firm grievance against firm clause no.11 was **not accepted**. 3. Firm provided affidavit stamped by notary public for firm wise clause no.19 (accept terms and condition of prequalification document).Hence, firm grievance was **accepted**. 4. Firm did not provide valid DRC for all the quoted items. Hence, firm grievance against item wise clause no. 2 was **not accepted** for all the quoted items. 5. Firm provided goods declaration certificates of endotracheal tubes with and without cuff and urine bag for relevant consecutive three years. Firm grievance was **accepted**. 6. Firm did not provide good declaration certificates of nasogastric tube for relevant consecutive three years. Hence, firm grievance was **not accepted**. Keeping in view the non-compliance of the requisite compulsory parameters, the grievances of the firm was rejected and upheld the decision of prequalification evaluation committee and status of the firm and its all quoted items is still declared as **"Not Prequalified"**
Hakimsons (Private) Limited	32	Endotrac heal tube (all sizes) Sterile Packs with cuff Set	Not Qualified	Drugs Sale License not provided. FBR income tax return/sales Tax return documents not provided. Clause#19. Affidavit is not stamped by notary public.	Not Prequalified	DRC Not provided. Goods declaration certificate for the last three year not attached.		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Hakimsons (Private) Limited	33	Endotracheal tube (all sizes) Sterile Packs without cuff Set	Not Qualified	Drugs Sale License not provided. FBR income tax return/sales Tax return documents not provided. Clause#19. Affidavit is not stamped by notary public.	Not Prequalified	DRC Not provided. Goods declaration certificate for the last three year not attached.		
Hakimsons (Private) Limited	59	Suction Catheter (All Sizes)	Not Qualified	Drugs Sale License not provided. FBR income tax return/sales Tax return documents not provided. Clause#19. Affidavit is not stamped by notary public.	Not Prequalified	DRC not provided		
Hakimsons (Private) Limited	63	Urine Bags Sterile (2000ml) Packs	Not Qualified	Drugs Sale License not provided. FBR income tax return/sales Tax return documents not provided. Clause#19. Affidavit is not stamped by notary public.	Not Prequalified	DRC Not provided. Goods declaration certificate for the last three year not attached.		
Hakimsons (Private) Limited	64	Volumetric Chamber (I.V Burette) Sterile Packs 100ml size	Not Qualified	Drugs Sale License not provided. FBR income tax return/sales Tax return documents not provided. Clause#19. Affidavit is not stamped by notary public.	not Prequalified	DRC not provided		
Hakimsons (Private) Limited	48	Nelton Catheter Sterile Packs	Not Qualified	Drugs Sale License not provided. FBR income tax return/sales Tax return documents not provided. Clause#19. Affidavit is not stamped by notary public.	not Prequalified	DRC not provided		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Hashir Surgical Services	37	Foley's catheter (all sizes) Sterile Packs All sizes	Not Qualified Financial Turnover as well as bank statement verification required		Not Prequalified	Quoted product is not tried and tested in local environment for at least three years	Sir, 1. Reference to the report, Serial No.85 inquiry No.37 Foley's Catheters brand name Uro Cath of M/s Jiangxi Fenglin Medical Technology Co., Ltd., China. i. In the column of result remarks found that "not qualified due to financial turn over as well as Bank Statement verification required". We have already submitted attested bank statements in original (uploaded & hard copies) as per criteria. We are again submitting the bank statements with account maintenance letter from concerned banks, sale tax returns and Income Tax returns. ii. The reason of rejection "Quoted product Foley Catheters brand name Uro Cath is not tried and tested in local environment for at least three years". We are attaching the orders copies again along with cheque of trial and tests in the local environment for the last three years. 2. Reference to the report, Serial No. 88, inquiry No.58 Sterile Surgical Blades of M/s TRINON Titanium GmbH, Germany. i. In the column of result remarks found that "not qualified due to financial turn over as well as Bank Statement verification required". We have already submitted attested bank statements in original (uploaded & hard copies) as per criteria. We are again submitting the bank statements with account maintenance letter from concerned banks, sale tax returns and Income Tax returns. ii. Reason of rejection "Date of issuance of sole agency is less than one year till the date of submission of PQD" of M/S TRINON Titanium GmbH, Germany. We are in mutual business relations with M/s TRINON Titanium GmbH, Germany since 2015. We are submitting the received authorizations letters from Principal manufacturer from 2015 to 2019. 3. Reference to the report, serial No.93, 94 & 95 Inquiry No.55, 54, 59, Spinal Needle sterile, Scalp Vein Set, Suction Catheter of M/s MEDITOP Corporation Sdn., Bhd., (A wholly owned subsidiary of TOP Corporation Japan); i. In the column of result remarks found that "not qualified due to financial turn over as well as Bank Statement verification required". We have already submitted attested bank statements in original (uploaded & hard copies) as per criteria. We are again submitting the bank statements with account maintenance letter from concerned banks, sale tax returns and Income Tax returns. ii. Reason of rejection "Invalid CE Certificate of MEDITOP Corporation Sdn., Bhd., Malaysia/ valid quality certificate not provided". Any manufacturer of medical device can manufacture its products from any of its subsidiary either inside the country or outside the country and the notified body will issue ISO 13485 with confirmation that the manufacturing company is the wholly subsidiary of Principal company. Meditop Corporation Sdn., Bhd., Malaysia, is the wholly subsidiary of TOP Corporation Japan and on the basis of submitted CE and ISO 13485 in Punjab Prequalification for the year 2020-21, the products of Meditop Corporation Sdn., Bhd., Malaysia have got the registration letter from Drug Regulatory Authority of Pakistan. Further we are attaching the Free Sale Certificate issued from the Ministry of Health, Labor and welfare Government of Japan of the applied products which proves that on the basis of TOP Corporation Japan's CE Certification, the products of MEDITOP Malaysia have got approval for marketing in Japan. 4. Reference to the report, serial No.96, inquiry No.35, product Face Mask Surgical brand name SHENGGUANG Surgical Face Mask of M/s Shengguang Medical Instruments Co., Ltd., China; i. In the column of result remarks found that "not qualified due to financial turn over as well as Bank Statement verification required". We have already submitted attested bank statements in original (uploaded & hard copies) as per criteria. We are again submitting the bank statements with account maintenance letter from concerned banks, sale tax returns and Income Tax returns. ii. Reason of rejection "Date of issuance of sole agency is less than one year till the date of submission of PQD" of M/s Shengguang Medical Instruments Co., Ltd., China. We are in mutual business relations with M/s Shengguang Medical Instruments Co., Ltd., China since 2017. We are submitting all the received authorizations from principal company. 5. Reference to the report, serial No.97, inquiry No.63 Product Urine Bag sterile brand name BIO BAG of M/s Jiangsu Kangjin Medical Instruments Co., Ltd., China; i. In the column of result remarks found that "not qualified due to financial turn over as well as Bank Statement verification required". We have already submitted attested bank statements in original (uploaded & hard copies) as per criteria. We are again submitting the bank statements with account maintenance letter from concerned banks, sale tax returns and Income Tax returns. ii. Reason of rejection "expire ISO 13485 of principal manufacturer M/s Jiangsu Kangjin Medical Instruments Co., Ltd., China". We have submitted the Embassy notarized ISO 13485 certificate. We are submitting again the valid ISO 13485 certificate as per criteria. We are looking forward to your kind considerations in this regard.	Mr. Malik Anees, Assistant Manager, from M/s Hashir Surgical Services attended the meeting and presented their grievance to the grievance redressal committee. The committee heard the view point of the representative of the firm which was examined in the light of Evaluation Report. The committee after due deliberation and discussion, keeping in view the evaluation criteria decided that: 1. The firm provided verified bank statement of FY 2019-20 of Firm's Title account, which was **accepted**. 2. The firm provided POs of "Urocath" as evidence that the quoted product is tried and tested in local environment for at least three years, which was **accepted**. Hence the status of the firm for Foley's catheter (all sizes) Sterile Packs All sizes, declared "Prequalified". 3. The firm provided sole agency agreement of the Principal TRINON Titanium GmbH that comply with criteria of the PQ Document, which was **accepted**. Hence the status of the firm for Sterilized Surgical Blades, declared "Prequalified". 4. The firm provided sole agency agreement of the Principal Shengguang Medical Instrument Co., Ltd. that comply with criteria of the PQ Document, which was **accepted**. Hence the status of the firm for Face Mask Surgical, declared "Prequalified". 5. The firm provided valid ISO 13485 certificate of the Principal Jiangsu Kangjin Medical Instruments Co. Ltd., which was **accepted**. Hence the status of the firm for Urine Bags, declared "Prequalified". 6. The Firm submitted CE certification with free sales certificate bearing the manufacturing facility of Scalp Vein Set, Spinal Needle and Suction Catheter, of Meditop Corporation Sdn. Bhd. Malaysia. Furthermore, firm submitted same in Drug regulatory Authority of Pakistan as a mandatory document for Enlistment of medical devices. In addition, firm also submitted valid enlistment certificate issued by Drug Regulatory Authority of Pakistan bearing Manufacturing facility i.e. Meditop Corporation Sdn. Bhd. Malaysia of same. Hence, grievance of the firm was **accepted**. Hence status of the firm declared "**Prequalified**" for all quoted items **except** I.V Cannula with Injection Port and Integrated Closing Cone: 18G, 20G, 22G & 24G.
Hashir Surgical Services	43	I.V. Sets Sterile blister Pack	Not Qualified Financial Turnover as well as bank statement verification required		Not Prequalified			
Hashir Surgical Services	64	Volumetric Chamber (I.V Burette) Sterile Packs 100ml size	Not Qualified Financial Turnover as well as bank statement verification required		Not Prequalified			
Hashir Surgical Services	58	Sterilized Surgical Blades Sterile Packs All Sizes	Not Qualified Financial Turnover as well as bank statement verification required	Date of issuance of Sole Agency Agreement is less than one year till the date of submission of PQD	Not Prequalified	Date of issuance of Sole Agency Agreement is less than one year till the date of submission of PQD		
Hashir Surgical Services	41	I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 22G	Not Qualified Financial Turnover as well as bank statement verification required		Not Prequalified	Verification of GD & PO along with registration is required.		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Hashir Surgical Services	42	I.V Cannula with/without Injection Port with Integrated Closing Cone Sterile Pack 24G	Not Qualified Financial Turnover as well as bank statement verification required		Not Prequalified	Verification of GD & PO along with registration is required.		
Hashir Surgical Services	39	I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 18G	Not Qualified Financial Turnover as well as bank statement verification required		Not Prequalified	Verification of GD & PO along with registration is required.		
Hashir Surgical Services	40	I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 20G	Not Qualified Financial Turnover as well as bank statement verification required		Not Prequalified	Verification of GD & PO along with registration is required.		
Hashir Surgical Services	55	Spinal Needle Sterile Packs All Sizes	Not Qualified Financial Turnover as well as bank statement verification required	Invalid CE certificate of Principle Meditop Corporation (Malaysia) Sdn. Bhd.	Not Prequalified	Valid quality Certificate not provided.		
Hashir Surgical Services	54	Scalp Vein Set Sterile Packs	Not Qualified Financial Turnover as well as bank statement verification required	Invalid CE certificate of Principle Meditop Corporation (Malaysia) Sdn. Bhd.	Not Prequalified	Valid quality Certificate not provided.		
Hashir Surgical Services	59	Suction Catheter (All Sizes)	Not Qualified Financial Turnover as well as bank statement verification required	Invalid CE certificate of Principle Meditop Corporation (Malaysia) Sdn. Bhd.	Not Prequalified	Valid quality Certificate not provided.		
Hashir Surgical Services	35	Face Mask Surgical	Not Qualified Financial Turnover as well as bank statement verification required	Date of issuance of Sole Agency Agreement is less than one year till the date of submission of PQD	Not Prequalified	Date of issuance of Sole Agency Agreement is less than one year till the date of submission of PQD		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Hashir Surgical Services	63	Urine Bags Sterile (2000ml) Packs	Not Qualified Financial Turnover as well as bank statement verification required	Expired ISO 13485 of Principle Jiangsu Kangjin Medical Instruments Co., Ltd;	Not Prequalified			
Hospital Services & Sales	1	Auto Disable (AD)/re-use prevention (RUP) Syringe 0.5ml with needle (Blister Pack)	Qualified		Not Prequalified	Quoted product is not tried and tested in local environment for at least three years; Copies of Goods Declaration certificates of quoted items of last three years not attached; Testing report of any WHO accredited laboratory for (AD)/(RUP) syringes not attached.	Sir, Reference of the Technical Evaluation report for the subjected tender uploaded on Healthcare website Dated: 13-11-2020. We are enclosing herewith Grievance Letter for your kind acceptance. Kindly reconsider your decision against us and a fair chance should be given to our above mentioned products. We look forward for a positive response from you.	Mr. Malik Bashir Ahmed, Distributor of M/s Hospital Services & Sales attended the meeting and presented their grievance to the grievance redressal committee. The committee heard the view point of the representative of the firm which was examined in the light of Evaluation Report. The committee after due deliberation and discussion, keeping in view the evaluation criteria decided that: 1. The firm provided WHO Performance Quality Safety certificates of the quoted items “Yushou” 0.5ml, 1ml, 3ml, 5ml & 10ml as substantial evidence for Testing report of any WHO accredited laboratory for (AD)/(RUP) syringes which were **accepted**. 2. The firm did not provide and the requisite copies of GDs and POs of the quoted items of last three years consecutively. Hence, the grievance of the firm was **rejected** and the decision of PQ evaluation committee was upheld as “**Not Prequalified**”.
Hospital Services & Sales	2	Auto Disable (AD)/re-use prevention (RUP) Syringe 1ml with needle (Blister Pack)	Qualified		Not Prequalified	Quoted product is not tried and tested in local environment for at least three years; Copies of Goods Declaration certificates of quoted items of last three years not attached; Testing report of any WHO accredited laboratory for (AD)/(RUP) syringes not attached.		
Hospital Services & Sales	5	Auto Disable (AD)/re-use prevention (RUP) Syringe 5ml with needle (Blister Pack)	Qualified		Not Prequalified	Quoted product is not tried and tested in local environment for at least three years; Copies of Goods Declaration certificates of quoted items of last three years not attached; Testing report of any WHO accredited laboratory for (AD)/(RUP) syringes not attached.		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Hospital Services & Sales	3	Auto Disable (AD)/re-use preventio n (RUP) Syringe 2/3ml with needle (Blister Pack)	Qualified		Not Prequalified	Quoted product is not tried and tested in local environment for at least three years; Copies of Goods Declaration certificates of quoted items of last three years not attached; Testing report of any WHO accredited laboratory for (AD)/(RUP) syringes not attached.		
Hospital Services & Sales	4	Auto Disable (AD)/re-use preventio n (RUP) Syringe 10ml with needle (Blister Pack)	Qualified		Not Prequalified	Quoted product is not tried and tested in local environment for at least three years; Copies of Goods Declaration certificates of quoted items of last three years not attached; Testing report of any WHO accredited laboratory for (AD)/(RUP) syringes not attached.		
Hospital Supply Corporation	63	Urine Bags Sterile (2000ml) Packs	Not Qualified	Annual finacial turn over documents not attached	Not Prequalified	Registration of the quoted item not attached; Undertaking for knock down clause 3,6,7,8,9 and 10 not as prescribed in PQD; Quoted product is not tried and tested in local environment for at least three years Copies of Goods; Declaration certificates of quoted items of last three years not attached	Reference of the Technical Evaluation report for the subjected tender uploaded on Healthcare website Dated: 13-11-2020. We are enclosing herewith Grievance Letter for your kind acceptance. Kindly reconsider your decision against us and a fair chance should be given to our above mentioned products. We look forward for a positive response from you.	Mr. Muhammad Hussain, Field Manager, from M/s Hospital Supply Corporation attended the meeting and presented their grievance to the grievance redressal committee. The committee heard the view point of the representative of the firm which was examined in the light of Evaluation Report. 1. The committee after due deliberation and discussion, keeping in view the evaluation criteria decided that: The firm provided undertaking for item-wise knock down clause 3,6,7,8,9 and 10 as prescribed in PQD, which were **accepted**. 2. The firm provided FBR Tax returns of FY 2017-18 & 2018-19 as substantial evidence to that its financial turnover is more that Rs. 300 Million, which was **accepted**. 3. The firm provided GDs of Volumetric Chamber (I.V Burette) 100ml size; I.V. Sets; Urine Bags, which were **accepted**. 4. The firm did not provided POs of all quoted items of last three years consecutively. Hence, the grievance of the firm was **rejected** and the decision of PQ evaluation committee was upheld as "**Not Prequalified**".

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Hospital Supply Corporation	64	Volumetric Chamber (I.V Burette) Sterile Packs 100ml size	Not Qualified	Annual finacial turn over documents not attached	Not Prequalified	Undertaking for knock down clause 3,6,7,8,9 and 10 not as prescribed in PQD; Quoted product is not tried and tested in local environment for at least three years Copies of Goods; Declaration certificates of quoted items of last three years not attached		
Hospital Supply Corporation	43	I.V. Sets Sterile blister Pack	Not Qualified	Annual finacial turn over documents not attached	Not Prequalified	Undertaking for knock down clause 3,6,7,8,9 and 10 not as prescribed in PQD; Quoted product is not tried and tested in local environment for at least three years Copies of Goods Declaration certificates of quoted items of last three years not attached		
Hospital Supply Corporation	54	Scalp Vein Set Sterile Packs	Not Qualified	Annual finacial turn over documents not attached	Not Prequalified	Undertaking for knock down clause 3,6,7,8,9 and 10 not as prescribed in PQD; Quoted product is not tried and tested in local environment for at least three years Copies of Goods Declaration certificates of quoted items of last three years not attached		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Hospital Supply Corporation	24	Disposable Insulin Syringe 1ml with needle (Blister Pack)	Not Qualified	Annual finacial turn over documents not attached	Not Prequalified	Undertaking for knock down clause 3,6,7,8,9 and 10 not as prescribed in PQD; Quoted product is not tried and tested in local environment for at least three years Copies of Goods Declaration certificates of quoted items of last three years not attached		
Hospital Supply Corporation	30	Disposable syringe 5ml with needle. (Blister pack)	Not Qualified	Annual finacial turn over documents not attached	Not Prequalified	Undertaking for knock down clause 3,6,7,8,9 and 10 not as prescribed in PQD; Quoted product is not tried and tested in local environment for at least three years Copies of Goods; Declaration certificates of quoted items of last three years not attached		
Hospital Supply Corporation	25	Disposable syringe 10ml with needle. (Blister pack)	Not Qualified	Annual finacial turn over documents not attached	Not Prequalified	Undertaking for knock down clause 3,6,7,8,9 and 10 not as prescribed in PQD; Copies of Goods; Declaration certificates of quoted items of last three years not attached		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Hospital Supply Corporation	27	Disposable Syringe 20ml with needle. (Blister pack)	Not Qualified	Annual finacial turn over documents not attached	Not Prequalified	Registration of the quoted item not attached; Undertaking for knock down clause 3,6,7,8,9 and 10 not as prescribed in PQD; Quoted product is not tried and tested in local environment for at least three years Copies of Goods; Declaration certificates of quoted items of last three years not attached		
Hospital Supply Corporation	28	Disposable Syringe 3ml with needle. (Blister pack)	Not Qualified	Annual finacial turn over documents not attached	Not Prequalified	Undertaking for knock down clause 3,6,7,8,9 and 10 not as prescribed in PQD; Copies of Goods; Declaration certificates of quoted items of last three years not attached		
IBL Healthcare Limited	63	Urine Bags Sterile (2000ml) Packs	Not Qualified	Annual finacial turn over documents not attached	Not Prequalified	Valid DRC /enlistment certificate not provided Undertakings are not provided on notarized stamp paper PO and GD for last three years not provided.	Respected Sir, It is stated with all due respect to your honorable chairman grievance committee that as per Evaluation report of Pre – qualification of medical devices dated 13-11-2020. We M/S IBL Healthcare Limited had been declared Not Pre qualified as firm wise as well as item wise. Your Honorable Evaluation team mentioned that our firm is not Pre qualified due to following reasons: FIRM WISE KNOCK DOWN Company Name Reason of Rejection Documents presented in Grievance IBL Healthcare Limited Undertakings not Legalized/Notarized Undertakings on valid legalized /Notarized stamp papers presented as per requirement for your kind consideration. do Annual Financial turnover docs not attached 3 years tax returns 2017, 2018 and 2019 attached. 1 year bank statement attached for your kind consideration. Knocked Down items Blood Transfusion Set Sr. No Inquiry No. Reason of rejection Docs presented in Grievance 113 14 Undertakings are not provided on notarized stamp paper Dear Sir we are presenting all of the undertakings on notarized stamp papers of knock down clauses no. 3, 6, 7, 8, 9 and 10 are attached for your kind consideration Do Do PO and GD for last 3 years not provided. GDs of 2017, 2018, 2019 and 2020 attached for your kind consideration. P.Os of 2018, 2019 and 2020 attached. IV Set Sterile blister Sr. No Inquiry No. Reason of rejection Docs presented in Grievance 116 43 Undertakings are not provided on notarized stamp paper Dear Sir we are presenting all of the undertakings on notarized stamp papers of knock down clauses no. 3, 6, 7, 8, 9 and 10 are attached for your kind consideration Do Do PO and GD for last 3 years not provided. GDs of 2016, 2019 and 2020 attached for your kind consideration. P.Os of 2020 attached. Blood Bags Sterile Pack 250 ml Single Sr. No Inquiry No. Reason of rejection Docs presented in Grievance 117 12 Undertakings are not provided on notarized stamp paper Dear Sir we are presenting all of the undertakings on notarized stamp papers of knock down clauses no. 3, 6, 7, 8, 9 and 10 are attached for your kind consideration Do Do PO and GD for last 3 years not provided. By name 250 GDs not attached. P.Os of 2019 and 2020 attached. Blood Bags Sterile Pack 500 ml Single Sr. No Inquiry No. Reason of rejection Docs presented in Grievance 118 13 Undertakings are not provided on notarized stamp paper Dear Sir we are presenting all of the undertakings on notarized stamp papers of knock down clauses no. 3, 6, 7, 8, 9 and 10 are attached for your kind consideration Do Do PO and GD for last 3 years not provided. GDs of 2019 and 2020 attached for your kind consideration. P.Os of 2019 and 2020 attached. SIR, IN THE LIGHT OF ABOVE MENTIONED FACTS AND CURRENT STATUS OF OUR FIRM WE HOPE THAT YOUR HONORABLE CHAIRMAN OF GRIEVANCES COMMITTEE CERTAINLY CONSIDER OUR SOLICITATION AND DECLARED OUR FIRM AND PRODUCTS PREQUALIFIED IN	Mr. Nouman Regional Manager from M/S IBL Healthcare Limited attended the meeting and presented their grievance to the grievance redressal committee. The committee heard the view point of the firm which was examined in the light of Evaluation Report. The committee after due deliberation and discussion, keeping in view the required parameters in detail decided that: 1. The firm provided FBR tax returns to substantiate its claim of having financial turnover more than 300 million rupees which was **accepted**. 2. The firm provided undertakings for firm wise knockdown criteria clause no 3,4,9,10,14,15,17&19 and item wise knockdown criteria clause no 3,6,7,8,9&10 on legalized and notarized stamp paper which was also accepted. Hence, grievance of the firm was **accepted**. 3. The firm provided GD certificates and Pos for consecutive three years for the quoted item Blood transfusion set sterile pack which were also **accepted**. 4. The Firm provided GD certificates and Pos for consecutive three years for the quoted item Blood bag sterile pack 250ml & 500 ml single. Hence, grievance of the firm was **accepted**. 5.The Firm provided GD certificates and Pos for consecutive three years for the quoted item IV set sterile pack. Hence, grievance of the firm was **accepted**. Keeping in view the compliance of the requisite compulsory parameters, the grievances of the firm was accepted and status of the firm is declared as "**Prequalified**" for all quoted items **except** Nasogastric tube all sizes, suction catheter & urine bag.

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
IBL Healthcare Limited	14	Blood Transfusion Set Sterile Packs	Not Qualified	Undertakings are not provided on notarized/legalized stamp paper	Not Prequalified	Undertakings are not provided on notarzied stamp paper. PO and GD for last three years not provided.	PRE – QUALIFICATION OF FOREIGN PRINCIPAL OF MEDICAL DEVICES. BEST REGARDS, ON THE BEHALF OF IBL Health care Ltd	
IBL Healthcare Limited	59	Suction Catheter (All Sizes)	Not Qualified	Undertakings are not provided on notarized/legalized stamp paper	Not Prequalified	Valid DRC /enlistment certificate not provided Undertakings are not provided on notarzied stamp paper. PO and GD for last three years not provided.		
IBL Healthcare Limited	47	Nasogastric tube (all sizes) Sterile Packs	Not Qualified	Undertakings are not provided on notarized/legalized stamp paper	Not Prequalified	Valid DRC /enlistment certificate not provided Undertakings are not provided on notarzied stamp paper. PO and GD for last three years not provided.		
IBL Healthcare Limited	43	I.V. Sets Sterile blister Pack	Not Qualified	Undertakings are not provided on notarized/legalized stamp paper	Not Prequalified	Undertakings are not provided on notarzied stamp paper. PO and GD for last three years not provided.		
IBL Healthcare Limited	12	Blood Bags Sterile Packs 250ml single	Not Qualified	Undertakings are not provided on notarized/legalized stamp paper	Not Prequalified	Undertakings are not provided on notarzied stamp paper. PO and GD for last three years not provided.		
IBL Healthcare Limited	13	Blood Bags Sterile Packs 500ml single	Not Qualified	Undertakings are not provided on notarized/legalized stamp paper	Not Prequalified	Undertakings are not provided on notarzied stamp paper. PO and GD for last three years not provided.		
Injection System (Pvt.) Ltd.			Not Qualified	Online PQOD not submitted	Not Prequalified	Online PQOD not submitted	We have no CE mark certificate, though we have applied for CE mark certification to UDEM Turkey via ACS Registar Pakistan, but due to COVID-19 the site visit is pending. We request you to kindly process and accept our application	No representative from injection system attended the meeting. The committee observed the viewpoint of the firm which was examined in the light of Evaluation Report.The committee after due delibberation and discussion,keeping in view the reqired parameters in detail,decided that: 1) The firm did not provide CE certificate which was **not accepted**. 2)The firm did not provide annual financial turnover document which was **not accepted**. 3) The firm did not provide Building fitness certificate or lay out plan approved by concern authority which was **not accepted**. 4)The firm did not provide notarized undertakings, which were **not accepted**. 5) The firm did not provide valid GMP which was **not accepted**. Keeping in view the non-compliance of the requisite compulsory parameters, the grievances of the firm was **rejected** and upheld the decision of prequalification evaluation committee and status of the firm and its all quoted items is still declared as "**Not Prequalified"**

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Intra health	56	Sterile Surgical Gloves Pairs 6 ½, 7, 7 ½ (Powdered)	Qualified		Prequalified		With due respect we submit here under few lines for your kind consideration. Reference to your Pre-Qualification Evaluation report Prequalification of Manufacturing Units & Sole Agents of Foreign Principals for Medical Devices 2020 – 2021 For DGHS, P&SHD. Tender Inquiry No. 44, 60 & 63 were Not Prequalified due to DRC not provided. We've already applied for DRC for the said items. The application forms are attached for your consideration. It is our request to look over this matter. Your cooperation in this regard will be much appreciated.	Mr. Shafaqat Ali BDM from Intra health attended the meeting and presented their grievance to the grievance redressal committee. The committee heard the view point of the representative of the firm which was examined in the light of Evaluation Report. The committee after due deliberation and discussion, keeping in view the required parameters in detail, decided that: 1) The firm applied for DRC for enlistment in DRAP for the said item inq. no. **63** (Urine Bags Sterile (2000ml) Packs), **44** (Instrumental Disinfectant Solution Of appropriate composition), and **60** (Surface Disinfectant Solution Of appropriate composition) since 07 oct, 2019 for the first time and currently not enlisted in DRAP list hence inq. no. 63, 44, and 60 were "**Not Prequalified" except** all other quoted items.
Intra health	34	Examination Gloves Latex (S.M.L)	Qualified		Prequalified			
Intra health	44	Instrumental Disinfectant Solution Of appropriate composition	Not Qualified		Not Prequalified	DRC not provided		
Intra health	60	Surface Disinfectant Solution Of appropriate composition	Not Qualified		Not Prequalified	DRC not provided		
Intra health	14	Blood Transfusion Set Sterile Packs	Qualified		Prequalified			
Intra health	43	I.V. Sets Sterile blister Pack	Qualified		Prequalified			
Intra health	63	Urine Bags Sterile (2000ml) Packs	Not Qualified		Not Prequalified	DRC not provided		
Intra health	64	Volumetric Chamber (I.V Burette) Sterile Packs 100ml size	Qualified		Prequalified			

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Iqbal and Company	21	CVP Line (Double Lumen) (For Dialysis)	Qualified		Not Prequalified	GD and PO not Provided for last three years.	Sir, Dear Sir, Assalamu Alaikum Wa Rahmatullahi Wa Barakatuhu In reference to your evaluation report we would like to submit our grievance and clarification as follows Objection on us are as below with clarification: 20 CVP Line (Double Lumen) All sizes GD and PO not Provided for last three years. Purchase order attached already and re-attaching for your kind review. (Annexure A) GD's attached and re-attaching for your kind review.(Annexure B) It is requested to kindly approve us for Item 20 for healthy competition as us product is DRAP registered. 21 CVP Line (Double Lumen) For Dialysis GD and PO not Provided for last three years. Purchase order attached already and re-attaching for your kind review. (Annexure C) GD's attached already and re-attaching for your kind review. (Annexure B) It is requested to kindly approve us for Item 21 for healthy competition as us product is DRAP registered Grievance Against M/S UDL & M/S BBraun Item 20 For Item 20 M/S UDL do not fulfill the requirement for purchase orders and GD's the same as mentioned for Item 21 whereas for Item 20 this point has not been addressed so it is requested to please look into the same. Please note that the prequalification advertised requirement is "CVP Line (Double Lumen) All Sizes. The reason behind mentioning "All sizes" is so that prequalification can be done of all sizes which will naturally benefit the government instead of qualifying just one size which is against the requirement. Where the above said companies have offered just one size in their offer which is violation of the bidding documents advertised specification. Along with the objection of GD's and purchase orders for Item 20 M/S UDL have mentioned that they are offering just one size i.e. 7Fr CVP Double Lumen against Item 20 whereas the requirement is of CVP Line (Double Lumen) All Sizes. In CVP Double Lumen there are various sizes like of 4 Fr,5Fr available which they have not offered therefore their offer is conditional and in complete and committee is requested to look into it because the requirement is "CVP Line (Double Lumen) All Sizes (Copy attached brochure showing the same Annex D) M/S BBraun have offered CERTOFIX DUO S 720 Double Lumen Central Venous Catheter meaning they also have just offered one size 7Fr (Copy attached Annex E) whereas requirement is of "All sizes". M/S BBraun also have other sizes available in CVP Double Lumen like Duo S 408,413,420,508,513,520,730,715 etc. Please see copy attached of brochure which they have not offered. (Copy attached Annex F). As M/S BBraun have offered just one size therefore it is not meeting the criteria of CVP Line (Double Lumen) All Sizes therefore their offer is conditional and committee is requested to look into it.	Mr. Tariq Lodhi, Branch Manager, from M/s Iqbal & Company attended the meeting and presented their grievance to the grievance redressal committee. The committee heard the view point of the representative of the firm which was examined in the light of Evaluation Report. The committee after due deliberation and discussion, keeping in view the evaluation criteria decided that: The firm provided GDs & POs for "Medcomp" of last three years consecutively, which were **accepted**. Hence the status of the firm for CVP Line (Double Lumen) (For Dialysis) & CVP Line (Double Lumen), declared "**Prequalified**". The grievance of the firm against M/s B.Braun and UDL was addressed to the extent that only the quoted size of the apllied items i.e. CVP Line (Double Lumen) (For Dialysis) & CVP Line (Double Lumen) shall stand prequalified.
Iqbal and Company	20	CVP Line (Double Lumen) (All Sizes)	Qualified		Not Prequalified	GD and PO not Provided for last three years.		
KM Enterprises	46	Male Latex Condom (UNFPA/ WHO prequalified)	Qualified		Not Prequalified	No GD certificate and No POs of relevant 3 years has been provided for the quoted item.	With reference to your Evaluation Report of pre-qualification dated 13.11.2020. We here by enclosed the all the required information & documents regarding the quires in the Prequalification evaluation report of our quoted products You are requested please re-evaluate our submitted documents and approve & pre-qualified our products . Thanking for your anticipation, Best regards KM Enterprises DR Hafiz Muhammad Afzal Distribution Incharge	Mr. Khalid Mehmood Managing Director from M/s KM Enterprise attended the meeting and presented their grievance to the grievance redressal committee. The committee heard the viewpoint of the firm which was examined in the light of Evaluation Report. The committee after due deliberation and discussion, keeping in view the required parameters in detail decided that: 1. The firm provided valid ISO 13485 certificate of the foreign principle Super Max Gloves Manufacturing SDN BDH Malaysia which was **accepted**. Hence grievance of the firm was **accepted** and status of Examination Gloves Latex changed to "**Prequalified**". 2. The firm did not provide CE certificate for the quoted items Volumetric Chamber 100 ml, Auto disable (AD)/reuse preventable (RUP) syringes 5ml, 1ml, 10ml, 2/3ml with needle and disposable Insulin syringe 1ml with needle. Hence grievance of the firm was **rejected**, and status of these quoted items remained as **"Not Prequalified"**. 3. The firm did not provide GD certificates and POs for consecutive three years for the quoted items **except** Disposable syringes 1ml, 3ml, 10ml and 20ml with needle. Hence grievance of the firm was **rejected**, and status of the quoted items remained as **"Not Prequalified" except** Disposable syringes 1ml, 3ml, 10ml and 20ml with needle and Examination Gloves Latex (S.M.L).
KM Enterprises	35	Face Mask Surgical	Qualified		Not Prequalified	DRC not provided.No GD certificate and No POs of relevant 3 years has been provided for the quoted item.		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
KM Enterprises	15	Caps Surgical	Qualified		Not Prequalified	DRC not provided.No Quality standard certificate for the quoted item. No GD certificate and No POs of relevant 3 years has been provided for the quoted item.		
KM Enterprises	63	Urine Bags Sterile (2000ml) Packs	Qualified		Not Prequalified	DRC not provided. No GD certificate and No POs of relevant 3 years has been provided for the quoted item.		
KM Enterprises	64	Volumetric Chamber (I.V Burette) Sterile Packs 100ml size	Not Qualified	CE certificate does not contain quoted item	Not Prequalified	No Quality standard certificate for the quoted item. No GD certificate and No POs of relevant 3 years has been provided for the quoted item.		
KM Enterprises	5	Auto Disable (AD)/re-use prevention (RUP) Syringe 5ml with needle (Blister Pack)	Not Qualified	CE certificate does not contain quoted item	Not Prequalified	No Quality standard certificate for the quoted item. No Quality standard certificate for the quoted item. No GD certificate and No POs of relevant 3 years has been provided for the quoted item. No Testing report of any WHO accredited laboratory has been provided.		
KM Enterprises	2	Auto Disable (AD)/re-use prevention (RUP) Syringe 1ml with needle (Blister Pack)	Not Qualified	CE certificate does not contain quoted item	Not Prequalified	No Quality standard certificate for the quoted item. No GD certificate and No POs of relevant 3 years has been provided for the quoted item. No Testing report of any WHO accredited laboratory has been provided.		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
KM Enterprises	4	Auto Disable (AD)/re-use preventio n (RUP) Syringe 10ml with needle (Blister Pack)	Not Qualified	CE certificate does not contain quoted item	Not Prequalified	No Quality standard certificate for the quoted item. No GD certificate and No POs of relevant 3 years has been provided for the quoted item. No Testing report of any WHO accredited laboratory has been provided.		
KM Enterprises	3	Auto Disable (AD)/re-use preventio n (RUP) Syringe 2/3ml with needle (Blister Pack)	Not Qualified	CE certificate does not contain quoted item	Not Prequalified	No Quality standard certificate for the quoted item No GD certificate and No POs of relevant 3 years has been provided for the quoted item. No Testing report of any WHO accredited laboratory has been provided.		
KM Enterprises	30	Disposabl e syringe 5ml with needle. (Blister pack)	Qualified		Prequalified			
KM Enterprises	28	Disposabl e Syringe 3ml with needle. (Blister pack)	Qualified		Not Prequalified	No GD certificate and No POs of relevant 3 years has been provided for the quoted item.		
KM Enterprises	24	Disposabl e Insulin Syringe 1ml with needle (Blister Pack)	Not Qualified	CE certificate does not contain quoted item	Not Prequalified	No Quality standard certificate for the quoted item. No GD certificate and No POs of relevant 3 years has been provided for the quoted item.		
KM Enterprises	25	Disposabl e syringe 10ml with needle. (Blister pack)	Qualified		Not Prequalified	No GD certificate and No POs of relevant 3 years has been provided for the quoted item.		
KM Enterprises	26	Disposabl e Syringe 1ml with needle (Blister Pack)	Qualified		Not Prequalified	No GD certificate and No POs of relevant 3 years has been provided for the quoted item.		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
KM Enterprises	27	Disposable Syringe 20ml with needle. (Blister pack)	Qualified		Not Prequalified	No GD certificate and No POs of relevant 3 years has been provided for the quoted item.		
KM Enterprises	37	Foley's catheter (all sizes) Sterile Packs All sizes	Qualified		Not Prequalified	No GD certificate and No POs of relevant 3 years has been provided for the quoted item.DRC not provided		
KM Enterprises	39	I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 18G	Qualified		Not Prequalified	No GD certificate and No POs of relevant 3 years has been provided for the quoted item.		
KM Enterprises	40	I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 20G	Qualified		Not Prequalified	No GD certificate and No POs of relevant 3 years has been provided for the quoted item.		
KM Enterprises	41	I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 22G	Qualified		Not Prequalified	No GD certificate and No POs of relevant 3 years has been provided for the quoted item.		
KM Enterprises	42	I.V Cannula with/without Injection Port with Integrated Closing Cone Sterile Pack 24G	Qualified		Not Prequalified	No GD certificate and No POs of relevant 3 years has been provided for the quoted item.		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
KM Enterprises	34	Examination Gloves Latex (S.M.L)	Not Qualified	Provided ISO 13485 certificates of the foreign principle SUPER MAX GLOVES MANUFACTRING SDN BDH Malaysia has been expired.	Not Prequalified	ISO 13485 certificate of the quoted item has been expired.		
KM Enterprises	45	IUCD (CU-T 380A) UNFPA/ WHO Prequalified	Qualified		Not Prequalified	NO GD certificates for the quoted item has been provided. POs for the quoted item for relevant 3 years has not been provided.		
Lab Link Enterprises	54	Scalp Vein Set Sterile Packs	Not Qualified	clause 8:valid CE certificate of Nipro Thailand not attached	Not Prequalified	CE certificate of Nipro thailand not provided	With reference to the prequalification evaluation report in which our firm was declared not prequalified for IV cannula 18 G, 20 G, and 22 G for not having experience of the last three years. It is submitted that we are an importer of NIPRO IV Cannula and we are importing it from the last 8 years continuously. Approximately all teaching hospitals and DHA s and other institutes are purchasing NIPRO IV cannula. We have already attached all the required documents for the experience of our products and we are attaching them again for consideration. 2. We are declared not Prequalified in Nipro Scalp Vein Set due to not attached CE Certificate. Now we are submitting a CE certificate of NIPRO THAILAND for scalp vein. Keeping in view of our submitted documents along with our grievance we are requesting to declare us prequalify for NIPRO IV Cannula 18G,20G, 22G, and Scalp Vein Set. Thanking you in anticipation.	Mr. Kashif Ahmad BDM from M/s Lab link attended the meeting and presented their grievance to the grievance redressal committee. The committee heard the view point of the firm which was examined in the light of Evaluation Report. The committee after due deliberation and discussion, keeping in view the required parameters in detail decided that: 1.The Firm provided POs for consecutive three year experience of quoted item IV Cannula 18G, 20G & 22G which was **accepted**. 2.The Firm submitted CE certification with annexure bearing the manufacturing facility of scalp vein set sterile pack of Nipro Thailand. Furthermore, firm submitted same in Drug regulatory Authority of Pakistan as a mandatory document for Enlistment of medical devices. In addition, firm also submitted valid enlistment certificate issued by Drug Regulatory Authority of Pakistan bearing Manufacturing facility i.e. Nipro Thailand of same, hence, **accepted**. 3.The Firm did not provide valid DRC of 50 ml syringe with needle which was **not accepted**. Keeping in view the compliance of the requisite compulsory parameters, the grievances of the firm was accepted and status of the firm is declared as "**Prequalified**' except 50ml syringe with needle.
Lab Link Enterprises	29	Disposable Syringe 50ml with needle. (Blister pack)	Not Qualified		Not Prequalified	Quoted item is disposable syringe with needle but as per Drug enlistment certificate ,without needle is approved		
Lab Link Enterprises	30	Disposable syringe 5ml with needle. (Blister pack)	Qualified		Prequalified			
Lab Link Enterprises	28	Disposable Syringe 3ml with needle. (Blister pack)	Qualified		Prequalified			
Lab Link Enterprises	27	Disposable Syringe 20ml with needle. (Blister pack)	Qualified		Prequalified			

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Lab Link Enterprises	24	Disposable Insulin Syringe 1ml with needle (Blister Pack)	Qualified		Prequalified			
Lab Link Enterprises	25	Disposable syringe 10ml with needle. (Blister pack)	Qualified		Prequalified			
Lab Link Enterprises	42	I.V Cannula with/without Injection Port with Integrated Closing Cone Sterile Pack 24G	Qualified		Prequalified			
Lab Link Enterprises	39	I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 18G	Qualified		Not Prequalified	PO for the last three years not attached		
Lab Link Enterprises	40	I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 20G	Qualified		Not Prequalified	PO for the last three years not attached		
Lab Link Enterprises	41	I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 22G	Qualified		Not Prequalified	PO for the last three years not attached		
Lab Link Enterprises	55	Spinal Needle Sterile Packs All Sizes	Qualified		Prequalified			

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
M & M Pharma.	45	IUCD (CU-T 380A) UNFPA/ WHO Prequalified	Qualified		Not Prequalified	Quoted product record of try and testing in local environment for at least three years. Ineligible item as per ITA 3.2 of PQD and also as per Application Submission Form.	SIR, WE M & M PHARMA IS ONE OF THE LEADING IMPORTER / SUPPLIER OF BIOLOGICALS / MEDICAL DEVICES IN PAKISTAN. WE ARE SUPPLYING QUALITY PHARMACEUTICALS TO THE PRIMARY & SECONDARY HEALTH CARE DEPARTMENT PUNJAB SINCE 2012. WE HAVE PARTICIPATED IN THE SUBJECT PREQUALIFICATION PROCESS. WE HAVE APPLIED FOR ABOVE MENTIONED DEVICES (WHO PREQUALIFIED). WE WERE DECLARED NON-RESPONSIVE. THE REMARKS AND CLARIFICATIONS THERETO ARE GIVEN BELLOW; I U C D (WHO PREQUALIFIED REASONS / REMARKS CLARIFICATION QUOTED PRODUCT RECORD OF TRY AND TESTING IN LOCAL ENVIRONMENT FOR AT LEAST THREE YEARS. WE M & M PHARMA WAS THE ONLY ONE TO BE DECLARED PREQULIFIED BY P & S HEALTHCARE DEPARTMENT PUNJAB IN 2018-2020 AS PER CRITERIA OF TESTING IN LOCAL ENVIRONMENT FOR AT LEAST THREE YEARS. (COPY ATTACHED A) COPY OF PURCHASE ORDERS (ATTACHED B) COPY OF IMPORT DOCUMENT / GD (ATTACHED C) INELIGIBLE ITEM AS PER ITA 3.2 OF PQD AND ALSO AS PER APPLICATION SUBMISSION FORM. THERE WAS NO SUCH ORDERS BY THE GOVERNMENT OF PAKISTAN. IF IT IS ANY ORDER, PLEASE PROVIDE. THE NEW TRADE POLICY WHICH REGULATE IMPORT/EXPORT IN COUNTRY IS ATTACHED FOR REFERENCE. (ATTACHED D) MALE LATEX CONDOM (WHO PREQUALIFIED) REASONS / REMARKS CLARIFICATION QUOTED PRODUCT RECORD OF TRY AND TESTING IN LOCAL ENVIRONMENT FOR AT LEAST THREE YEARS. WE M & M PHARMA WAS ONLY ONE TO BE DECLARED PREQULIFIED BY P & S HEALTHCARE DEPARTMENT PUNJAB IN 2018-20 AS PER CRITERIA OF TESTING IN LOCAL ENVIRONMENT FOR AT LEAST THREE YEARS. (COPY ATTACHED E) COPY OF PURCHASE ORDERS (ATTACHED F) COPY OF IMPORT DOCUMENT / GD (ATTACHED G) LOOKING FORWARD FOR POSITIVE RESPONSE. M & M PHARMA 18TH NOVEMBER 2020	Mr. Muhammad Raheel Munawar Managing Director from M/s M & M Pharma attended the meeting and presented their grievance to the grievance redressal committee. The committee heard the viewpoint of the firm which was examined in the light of Evaluation Report. The committee after due deliberation and discussion, keeping in view the required parameters in detail decided that: 1. The firm provided SRO Dated 25-09-2020 by Governnment of Pakistan Ministry of Commerce Rule no. 5 (2a) " goods of Indian or Israeli origin or imported from India or Israel: Provided that provisions of this clause to the extent of India shall not apply to therapeutic products regulated by the Drug Regulatory Authority of Pakistan". Furthermore, the firm also submitted DRAP registration of the quoted product Pro Green imported from indian principle HLL Lifecare. Hence grievance of the firm was **accepted** to the extent of this parameter. 2. The firm did not provide GD certificates and POs for consecutive three years for the quoted items IUCD and Male Latex Condom. Hence grievance of the firm was **rejected**, and status of quoted items IUCD and Male Latex Condom remained as **"Not Prequalified"**.
M & M Pharma.	46	Male Latex Condom (UNFPA/ WHO prequalified)	Qualified		Not Prequalified	Quoted product record of try and testing in local environment for at least three years is not complete.		
MEDCO Healthcare			Not Qualified	Online PQOD not submitted	Not Prequalified	Online PQOD not submitted	Respected Sir, This is in reference your Technical Evaluation of Prequalification (SOLE AGENTS OF FOREIGN PRINCIPALS FOR MEDICAL DEVICES 2020-2021 FOR DGHS, P&SHD) According to the Technical Evaluation M/S MEDCO HEALTH CARE, has not qualified for prequalification, we feel honor to submit the Documents. Sir, due to login ID we have been troubling to up load the documents as per required. Sir, it is requested to you that our hard copy documents accept for technical evaluation. Or allow these documents to be accepted and uploaded. All the documents are submitted in shape of hard copy. In the light of above said facts please review and consider our case and change our status from not qualified to QUALIFIED to serve your esteemed organization for the next episode accordingly. Looking forward for your kind consideration in this regard. Thanks and Regards For MEDCO HEATH CARE, KARACHI M. Awais Sadiq GM CC:Director General Health Services Punjab	No representative from M/S MEDCO Healthcare attended the meeting and presented their grievance to the grievance redressal committee. The committee after due deliberation and discussion, keeping in view the required parameters in detail decided that: 1.Firm did not submit prequalification documents on online portal (PQOD) of P&SHD . Moreover, firm failed to apply grievance in hardcopy and on online. Further, turnover of the firm is less than 300 million as per FBR documents, and valid DSL is not provided in hard copy before grievance. Hence, grievance of the firm was **not accepted**. Keeping in view the non-compliance of the requisite compulsory parameters, the grievances of the firm was **rejected** and status of the firm is still declared as "**Not Prequalified**" .

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Medinostic Health Care (Pvt.) Ltd.	60	Surface Disinfectant Solution Of appropriate composition	Not Qualified Financial Turnover as well as bank statement verification required	clause 15: Undertaking not notarized. clause 11: Annual financial turn over is less than 300 million. clause 9: Address of storage facility is not mentioned on undertaking	Not Prequalified	GD for the last three years not provided	With reference to your evaluation report of the above mentioned reference prequalification. It is to bring in your kind knowledge that below mentioned are the justifications and replies to your objections. A. Firm Wise (Medimark Scientific) 1. Financial Turnover as well as bank statement verification required: a. As per clause 11 of PQOD. We have already submitted FBR Sales Tax Return as well as Bank Statement in our prequalification application that the financial turnover of the company is more than 300 million (Rs. 318 Million) for the fiscal year 2019 – 20. For your convenience, some additional documents are also enclosed with this letter for further clarification. • Audited Balance Sheet. • Turnover certificate from bank. • Bank Statements • FBR Sales Tax Return. 2. Clause 15: Undertaking not notarized. a. We have uploaded all notarized undertaking including clause 15 on the portal of PQOD at the time of prequalification application & same was submitted in Hardcopy. For your convenience, resubmitting the copy of said document. 3. Clause 9: Address of storage facility is not mentioned on undertaking. a. Our storage facility is situated on same location as our registered office that is why address was not mentioned separately on it. For your convenience undertaking with complete address of storage facility is attached for your kind perusal. B. Product Wise Item# 44. Reprodis HLD4I & Item.# 60. ChemGene HLD4H). 4. GD for last three years not provided. a. We have working this Principal since 2016 as per submitted copy of Principal authority letter. Also the copies of GDs has already been submitted in our prequalification application is from 2017, 2018 & 2020 which covers the requirement of 3 years. Resubmitting the copies of GDs with this letter. C. Firm Wise (Pal International) 5. Clause 12:pal international chamber of commerce document not attached. a. Online verification from relevant chamber has already been submitted in our prequalification application. For your convenience, copy of chamber of commerce certificate is enclosed with this letter. D. Product Wise Item# 15. Caps Surgical (Pal Mob Cap). 6. DRC not provided. a. The product “Pal Mob Cap” that we have applied for, are not classified as Medical Devices. Hence DRC may not be applicable. Statement regarding DRC certificate is already submitted in our prequalification application. 7. No PO (PUBLIC SECTOR) for past three-year experience in public sector attached. a. We are supplying the following products from the same Principal in Leading Public Sector institutions & Purchase Orders are attached. As you know that Surgical Caps are not Drug item therefore we quoted through our Local distributors. (Few POs are attached with this Letter for Ready reference). i. Medipal Alcohol Wipes ii. Medipal chlorhexidine Skin Wipes iii. Surgical Caps. 8. Clause 11: GD for year 2017 and 2018 not attached. a. We have been regularly import other products from same Principal since 2016. We hope that we have satisfied the observations made in the Evaluation Report and on the basis of the explanations given and documents submitted again with this letter, It is requested that Please Pre-Qualified our firm with all the quoted items	Mr. Ghulam Mustafa ASM from M/S Medinostic Health Care (Pvt.) Ltd attended the meeting and presented their grievance to the grievance redressal committee. The committee heard the view point of the firm which was examined in the light of Evaluation Report.The committee after due deliberation and discussion, keeping in view the required parameters in detail decided that: 1. The Firm provided FBR sales return for year 2020 and account maintenance certificate of Meezan bank for annual financial turnover(July 2019-June 2020)which was above 300 million rupees. Hence, grievance of the firm was **accepted**. 2. The Firm provided undertakings for firm wise knock down criteria clause No. 9 & 15 which was also **accepted**. 3. The Firm did not provide certificate of registration with chamber of commerce of PAL international. Hence, grievance of the firm was **not accepted**. 4. The Firm did not provide GDs for three consecutive years for quoted items instrumental disinfectant solution of appropriate composition & surface disinfectant solution of appropriate composition. Hence, grievance of the firm was **not accepted**. 5. Firm did not provide valid drug enlistment certificate, GDs and POs for consecutive three years for the quoted item surgical cap which was **not accepted**. Keeping in view the non-compliance of the requisite compulsory parameters, the grievances of the firm was **rejected** and status of the firm is declared as "**Not Prequalified**"
Medinostic Health Care (Pvt.) Ltd.	44	Instrumental Disinfectant Solution Of appropriate composition	Not Qualified Financial Turnover as well as bank statement verification required	clause 15: Undertaking not notarized. clause 11: Annual financial turn over is less than 300 million. clause 9: Address of storage facility is not mentioned on undertaking	Not Prequalified	GD for the last three years not provided		
Medinostic Health Care (Pvt.) Ltd.	15	Caps Surgical	Not Qualified Financial Turnover as well as bank statement verification required	clause 15: Undertaking not notarized. clause 11: Annual financial turn over is less than 300 million. clause 9: Address of storage facility is not mentioned on undertaking clause 12:pal international chamber of commerce document not attached	Not Prequalified	clause 2: DRC not provided Clause 5: No PO (PUBLIC SECTOR)for past three year experience in public sector attached Clause 11: GD for year 2017 and 2018 not attached		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Nipro Medical Pvt Ltd	38	Hollow Fiber Dialyzer (All Sizes) Individuall y Sterile Packed (with BTL and A.V Fistula Needle Pair)	Not Qualified		Not Prequalified	PO & GD for last three years not provided.	1. Firm wise Reason of rejection Annual financial turnover is less than 300 million Our Clarification Under umbrella of Nipro Corporation Japan; we are serving in Pakistan; since more than last 25 years to enhance and improve the quality of lives of people. Keeping in view the increased demand of quality medical devices in Pakistan our management decided to incorporate wholly owned subsidiary here for patient care. We have established Nipro Medical (Pvt) Ltd in Pakistan to serve patients at larger scale. Being a multinational company many of our customers are doing business with us on C&F basis. Taking into account the direct sale of only dialysis items our financial turnover is more than 300 million PKR. Detail of some direct sale is as below. 1. The Kidney Centre Karachi PO. No & Date: 41, 20/03/2020 (Dialyzer) PO Amount $: 134,162 Conversion @ 160 = Rs. 20,795,110 2. Tabba Kidney Institute PO. Date: 03/02/2020 (Dialyzer + BTS+ AVF) PO Amount $: 185,250 Conversion @ 160 = 29,640,000 3. Tabba Kidney Institute PO. Date: 03/02/2020 (Dialyzer + BTS+ AVF) PO Amount $: 66,300 Conversion @ 160 = 10,608,000 4. Sindh Institute of Urology and Transplantation PO No & Date: 91, 19/12/2019 (Dialyzer) PO Amount $: 533,520 Conversion @ 160 = 85,363,200 5. Sindh Institute of Urology and Transplantation PO No & Date: 120, 19/02/2020 (AVF) PO Amount $: 45,000 Conversion @ 160 = 7,200,000 6. Sindh Institute of Urology and Transplantation PO No & Date: 114, 13/02/2020 (Dialyzer) PO Amount $: 681,500 Conversion @ 160 = 109,040,000 7. Sindh Institute of Urology and Transplantation PO No & Date: 21, 31/08/2020 (AVF) PO Amount $: 43,501 Conversion @ 160 = 6,960,160 8. Sindh Institute of Urology and Transplantation PO No & Date: 25, 11/09/2020 (Dialyzer) PO Amount $: 424,203 Conversion @ 160 = 67,872,480 9. Sindh Institute of Urology and Transplantation PO No & Date: 01, 07/02/2019 (Dialysis Machines) PO Amount $: 97,500 Conversion @ 160 = 15,600,000 10. Total amount of above mentioned PO is 2,210,936US$ Conv. @ 160 = 353,078,950 1. Item wise Reason of rejection PO & GD for last three years not provided. Our Clarification Item wise POs and GDs were attached in web portal as well with hard copy, please find enclosed herewith the duplicate copies of item wise POs & GPs. 1. Our Reservation Item No. 38 (Hollow Fiber Dialyzer (All Sizes) individually sterile packed with BTL and AVF Fistula Needle pair) M/s Fresenius Medical Care is pre-qualified in item no. 38 whereas they are rejected in item no. 6 (AVF). Furthermore, item 06 (AVF) is also part of item no 38 hence they should be rejected in item no. 38 as well. On the basis of above clarification, we hereby request you for the acceptance of our firm and our quoted items as there is no other technical short fall with respect to the prequalification evaluation criteria and it does not have any impact on the product quality. Further our all other products of Nipro brand qualified and declares prequalified which assure our brand quality.	Mr Saleem Majeed (Managing Director) from M/s Nipro Medical (Pvt) Ltd. attended the meeting and presented their grievance to the grievance redressal committee. The committee heard the viewpoint of the firm which was examined in the light of Evaluation Report. The committee after due deliberation and discussion, keeping in view the required parameters in detail decided that: 1)The firm's annual turnover was less than Rs. 300 million.The firm did not provide FBR documents. 2)The firm provided PO and GD of Hollow fibre dialyzer for relevant last three years which was **accepted**. 3)The firm did not provided PO and GD of AV Fistula Needles which was **not accepted**. 4) The firm did not provided PO and GD of AV Set Blood tubing lining which was **not accepted**. Hence grievance of the firm was rejected, and status of all quoted items remained as **"Not Prequalified**".
Nipro Medical Pvt Ltd	6	AV Fistula Needles (Arterial+ venous) with fixed wings. (Individual ly Sterile Packed) size 16/17G.	Not Qualified	Annual financial turn over is less than 300 million	Not Prequalified	PO & GD for last three years not provided.		
Nipro Medical Pvt Ltd	7	AV Set Blood Tubing Lining (6.3-6.6mm) with one transduce r protector (Fluid Barrier) & Pre-Pump Arterial Pressure Monitorin g Line (Individual ly Sterile Packed).	Not Qualified	Annual financial turn over is less than 300 million	Not Prequalified	PO & GD for last three years not provided.		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Nisa . SF	25	Disposable syringe 10ml with needle. (Blister pack)	Not Qualified	Clause 8:CE certificate not attached,Clause 9:not legalized and address of storage facility not mentioned on undertaking, Clause 10:statment not correct(annexure A,B not mentioned on undertaking), Clause 11:annual financial turnover is less than 300 million ,bank statement is ok but not attested by bank, Clause 13:building fitness	Not Prequalified	Clause 1:QCS not attached,Clause 5:PO for last three years not provided.	Reference to subject : PRE-QUALIFICATION EVALUATION REPORT PREQUALIFICATION OF MANUFACTURING UNITS AND SOLE AGENTS OF FOREIGN PRINCIPALS FOR MEDICAL DEVICES 2020-2021 FOR DGHS, P&SHD Reason of Not Qualified : From serial # 178-183. Clause 8:CE certificate not attached, Clause 9:not legalized and address of storage facility not mentioned on undertaking, Clause 10:statment not correct(annexure A,B not mentioned on undertaking), Clause 11:annual financial turnover is less than 300 million ,bank statement is ok but not attested by bank, Clause 13:building fitness certificate not issued by concerned authority, Clause 15: Statement of undertaking according to PQD. Please find enclosed attachment: Clause 9:legalized and address of storage facility mentioned on undertaking, (Undertaking Attached). Clause 10: correct statement (annexure A,B mentioned on undertaking), (Undertaking Attached). Clause 11:annual financial turnover is not less than 300 million (bank statement attached attested by bank). Clause 13:building fitness certificate issued by concerned authority, (Building Certificate Attach approved by DRAP Authority. Clause 15: Statement of undertaking according to PQD. (Undertaking Attached). Please Find an attachment of all above documents Combine in PDF. Your kind cooperation in this regard will be highly appreciated.	Mr. Ijaz Khan, National Sales Maneger from M/s Nisa. SF attended the meeting and presented their grievance to the grievance redressal committee. The committee heard the view point of the representative of the firm which was examined in the light of Evaluation Report. The committee after due deliberation and discussion, keeping in view the required parameters in detail, decided that: 1. The firm did not attached the CE certificate in compliance to the Clause 8 of the firm wise knock down criteria, hence the grievance of the firm was **rejected**. 2. The firm attached the affidavit in compliance to the Clause 9 of firm wise knock down criteria and **accepted**. 3. The firm attached the affidavit in compliance to the Clause 10 of firm wise knock down criteria and **accepted**. 4. The firm provided the verified banck statements in compliance to the clause 11, hence thr grievance of the frim was **accepted**. 5. The firm attached the building fitness certificate in compliance to the clause 13 of firm wise knock down criteria and **accepted**. 6. The firm attached the affidavit in compliance to the Clause 15 of firm wise knock down criteria and **accepted**. 7. The firm did not submitted any documentary evidence in compliance to clause 5 (GDs and POs of last three years consecutively) of item wise knock down criteria for Item No. 25 (Disposable syringe 10ml with needle. (Blister pack)), 26 (Disposable syringe 1ml with needle. (Blister pack)), 27 (Disposable syringe 20ml with needle. (Blister pack)), 28 (Disposable syringe 3ml with needle. (Blister pack)), 30 (Disposable syringe 5ml with needle. (Blister pack)) and 43 (I.V. Sets Sterile blister Pack), hence the grievance of the firm was **rejected**. Keeping in view the non-compliance of the requisite compulsory parameters, the grievances of the firm was **rejected** and upheld the decision of prequalification evaluation committee and status of the firm is still declared as "**Not Prequalified**"
Nisa . SF	27	Disposable Syringe 20ml with needle. (Blister pack)	Not Qualified	Clause 8:CE certificate not attached,Clause 9:not legalized and address of storage facility not mentioned on undertaking, Clause 10:statment not correct(annexure A,B not mentioned on undertaking), Clause 11:annual financial turnover is less than 300 million ,bank statement is ok but not attested by bank, Clause 13:building fitness	Not Prequalified	Clause 1:QCS not attached,Clause 5:PO for last three years not provided.		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Nisa . SF	26	Disposable Syringe 1ml with needle (Blister Pack)	Not Qualified	Clause 8:CE certificate not attached,Clause 9:not legalized and address of storage facility not mentioned on undertaking, Clause 10:statment not correct(annexure A,B not mentioned on undertaking), Clause 11:annual financial turnover is less than 300 million ,bank statement is ok but not attested by bank, Clause 13:building fitness	Not Prequalified	Clause 1:QCS not attached,Clause 5:PO for last three years not provided.		
Nisa . SF	28	Disposable Syringe 3ml with needle. (Blister pack)	Not Qualified	Clause 8:CE certificate not attached,Clause 9:not legalized and address of storage facility not mentioned on undertaking, Clause 10:statment not correct(annexure A,B not mentioned on undertaking), Clause 11:annual financial turnover is less than 300 million ,bank statement is ok but not attested by bank, Clause 13:building fitness	Not Prequalified	Clause 1:QCS not attached,Clause 5:PO for last three years not provided.		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Nisa . SF	30	Disposable syringe 5ml with needle. (Blister pack)	Not Qualified	Clause 8:CE certificate not attached,Clause 9:not legalized and address of storage facility not mentioned on undertaking, Clause 10:statment not correct(annexure A,B not mentioned on undertaking), Clause 11:annual financial turnover is less than 300 million ,bank statement is ok but not attested by bank, Clause 13:building fitness	Not Prequalified	Clause 1:QCS not attached,Clause 5:PO for last three years not provided.		
Nisa . SF	43	I.V. Sets Sterile blister Pack	Not Qualified	Clause 8:CE certificate not attached,Clause 9:not legalized and address of storage facility not mentioned on undertaking, Clause 10:statment not correct(annexure A,B not mentioned on undertaking), Clause 11:annual financial turnover is less than 300 million ,bank statement is ok but not attested by bank, Clause 13:building fitness	Not Prequalified	Clause 1:QCS not attached,Clause 5:PO for last three years not provided.		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Nisa Impex (Private) Limited	43	I.V. Sets Sterile blister Pack	Not Qualified	clause 15. undertaking that none of its manufactured batch sample has been declared Spurious/Adulterated since 2017 onward is not provide. only given for quoted items and for last 2 years.	Not Prequalified		PRE-QUALIFICATION EVALUATION REPORT PREQUALIFICATION OF MANUFACTURING UNITS AND SOLE AGENTS OF FOREIGN PRINCIPALS FOR MEDICAL DEVICES 2020-2021 FOR DGHS, P&SHD Reason of Not Qualified : From serial # 184-196. Clause 15. undertaking that none of its manufactured batch sample has been declared Spurious/Adulterated since 2017 onward is not provide. only given for quoted items and for last 2 years. Please find enclosed clause 15. undertaking that none of its manufactured batch sample has been declared Spurious/Adulterated since 2017 onward. On duly attested Rs 100 stamp paper. Your kind cooperation in this regard will be highly appreciated.	"Mr. Eijaz Khan NSM from M/s Nisa. Impex attended the meeting and presented their grievance to the grievance redressal committee. The committee heard the view point of the representative of the firm which was examined in the light of Evaluation Report. The committee after due deliberation and discussion, keeping in view the required parameters in detail, decided that: 1) The firm provided undertaking of clause 15 which was **accepted**. Hence status of the firm declared "**Prequalified**" for all quoted items, **except** inq. no. 2 Auto Disable (AD)/re-use prevention (RUP) Syringe 1ml with needle (Blister Pack), inq. no. 3 Auto Disable (AD)/re-use prevention (RUP) Syringe 2/3ml with needle (Blister Pack), inq. no. 4 Auto Disable (AD)/re-use prevention (RUP) Syringe 10ml with needle (Blister Pack), inq. no. 5 Auto Disable (AD)/re-use prevention (RUP) Syringe 5ml with needle (Blister Pack).
Nisa Impex (Private) Limited	2	Auto Disable (AD)/re-use preventio n (RUP) Syringe 1ml with needle (Blister Pack)	Not Qualified	clause 15. undertaking that none of its manufactured batch sample has been declared Spurious/Adulterated since 2017 onward is not provide. only given for quoted items and for last 2 years.	Not Prequalified	No Testing report of any WHO accredited laboratory for Auto-disable (AD)/re-use prevention (RUP) syringes are available. no PO and GD certificates are available		
Nisa Impex (Private) Limited	3	Auto Disable (AD)/re-use preventio n (RUP) Syringe 2/3ml with needle (Blister Pack)	Not Qualified	clause 15. undertaking that none of its manufactured batch sample has been declared Spurious/Adulterated since 2017 onward is not provide. only given for quoted items and for last 2 years.	Not Prequalified	No Testing report of any WHO accredited laboratory for Auto-disable (AD)/re-use prevention (RUP) syringes are available. no PO and GD certificates are available		
Nisa Impex (Private) Limited	4	Auto Disable (AD)/re-use preventio n (RUP) Syringe 10ml with needle (Blister Pack)	Not Qualified	clause 15. undertaking that none of its manufactured batch sample has been declared Spurious/Adulterated since 2017 onward is not provide. only given for quoted items and for last 2 years.	Not Prequalified	No Testing report of any WHO accredited laboratory for Auto-disable (AD)/re-use prevention (RUP) syringes are available. no PO and GD certificates are available		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Nisa Impex (Private) Limited	5	Auto Disable (AD)/re-use preventio n (RUP) Syringe 5ml with needle (Blister Pack)	Not Qualified	clause 15. undertaking that none of its manufactured batch sample has been declared Spurious/Adult erated since 2017 onward is not provide. only given for quoted items and for last 2 years.	Not Prequalified	No Testing report of any WHO accredited laboratory for Auto-disable (AD)/re-use prevention (RUP) syringes are available. no PO and GD certificates are available		
Nisa Impex (Private) Limited	24	Disposabl e Insulin Syringe 1ml with needle (Blister Pack)	Not Qualified	clause 15. undertaking that none of its manufactured batch sample has been declared Spurious/Adult erated since 2017 onward is not provide. only given for quoted items and for last 2 years.	Not Prequalified			
Nisa Impex (Private) Limited	25	Disposabl e syringe 10ml with needle. (Blister pack)	Not Qualified	clause 15. undertaking that none of its manufactured batch sample has been declared Spurious/Adult erated since 2017 onward is not provide. only given for quoted items and for last 2 years.	Not Prequalified			
Nisa Impex (Private) Limited	26	Disposabl e Syringe 1ml with needle (Blister Pack)	Not Qualified	clause 15. undertaking that none of its manufactured batch sample has been declared Spurious/Adult erated since 2017 onward is not provide. only given for quoted items and for last 2 years.	Not Prequalified			

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Nisa Impex (Private) Limited	27	Disposable Syringe 20ml with needle. (Blister pack)	Not Qualified	clause 15. undertaking that none of its manufactured batch sample has been declared Spurious/Adulterated since 2017 onward is not provide. only given for quoted items and for last 2 years.	Not Prequalified			
Nisa Impex (Private) Limited	28	Disposable Syringe 3ml with needle. (Blister pack)	Not Qualified	clause 15. undertaking that none of its manufactured batch sample has been declared Spurious/Adulterated since 2017 onward is not provide. only given for quoted items and for last 2 years.	Not Prequalified			
Nisa Impex (Private) Limited	29	Disposable Syringe 50ml with needle. (Blister pack)	Not Qualified	clause 15. undertaking that none of its manufactured batch sample has been declared Spurious/Adulterated since 2017 onward is not provide. only given for quoted items and for last 2 years.	Not Prequalified			
Nisa Impex (Private) Limited	30	Disposable syringe 5ml with needle. (Blister pack)	Not Qualified	clause 15. undertaking that none of its manufactured batch sample has been declared Spurious/Adulterated since 2017 onward is not provide. only given for quoted items and for last 2 years.	Not Prequalified			

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Nisa Impex (Private) Limited	31	Disposable Syringe 60ml with Central Nozzle or Catheter Tip (Blister Pack)	Not Qualified	clause 15. undertaking that none of its manufactured batch sample has been declared Spurious/Adulterated since 2017 onward is not provide. only given for quoted items and for last 2 years.	Not Prequalified			
Noor International	56	Sterile Surgical Gloves Pairs 6 ½, 7, 7 ½ (Powdered)	Not Qualified	Expired 13485 of Principle Kossan International SDN. BHD.Annual Financial turnover is less than 300 million	Not Prequalified	Copies of Goods Declaration certificates of quoted items of last three years not attached; Undertaking for knockdown clause 3,6,7,8,9 and 10 not as prescribed in PQD	Sir, Reference to your Technical Evaluation report regarding PRE-QUALIFICATION OF MANUFACTURING UNITS AND SOLE AGENTS OF FOREIGN PRINCIPALS FOR MEDICAL DEVICES 2020-2021 FOR DGHS, P&SHD. Dated: 13-11-2020, the committee declared NOOR INTERNATIONAL as “Not Pre-Qualified” due to “Expired and Not Attached Required Documents” in His Technical evaluation results. Bid inquiry nos of items are written below: Item inquiry # 56 : Sterile Surgical Gloves Pairs 6 ½, 7, 7 ½ (Powdered) Result of Evaluation : Not Pre-Qualified Reason : (i) Due to Expired 13485 of Principle Kossan International SDN. BHD. (COPY ATTACHED) (ii) Annual Financial turnover is less than 300 million (COPY OF I.TAX RETURN 2018-19 ATTACHED) (iii)Copies of Goods Declaration certificates of quoted items of Last three years not attached; (COPIES ATTACHED) (iv) Undertaking for knockdown clause 3, 6,7,8,9 and 10 not as Prescribed in PQD (ORIGINAL ATTACHED) Item inquiry # 55 : Spinal Needle Sterile Packs All Sizes Result of Evaluation : Not Pre-Qualified Reason :(i) Annual Financial turnover is less than 300 million (COPY OF I.TAX RETURN 2018-19 ATTACHED) (ii) Copies of Goods Declaration certificates of quoted items of Last three years not attached; (COPIES ATTACHED) (iii) Undertaking for knockdown clause 3, 6,7,8,9 and 10 not as Prescribed in PQD (ORIGINAL ATTACHED) Sir, this is to bring into your kind notice that, all the required documents were attached with our Proposal and the same are again attached with This Grievance Letter for your kind consideration. Furthermore, our brands (Kossan International & Unisis Corp.) are of high quality with having all International Quality Standard Certificates and use by number of Hospitals in all over Pakistan (Purchase orders already attached) It is therefore requested to review your decision in light of attached documents and kindly reconsidered our items and declare NOOR INTERNATIONAL as “Qualified”. Thanks for your obligation in advance. Yours Truly, For Noor International Manager Sales	No representative of M/s Noor International attended the meeting and presented their grievance to the grievance redressal committee. The committee in the light of Evaluation Report examined the grievance application of the firm. The committee after due deliberation and discussion, keeping in view the evaluation criteria decided that: 1. The firm provided FBR Tax Returns of FY 2017-18 & FY 2018-19 reflecting financial turnover more than Rs.300 Million, which was **accepted**. 2. The firm provided undertakings for knockdown clause 3,6,7,8,9 and 10 as prescribed in PQD, which were **accepted**. 3. The firm provided valid ISO 13485 certificate of the Principal Kossan International Sdn. Bhd. Malaysia, which was **accepted**. 4. The firm provided copies of GD mentioning name of supplier “QZF General Trading, Dubai” instead of “Unisis Corp. Japan.” and “Kossan International Sdn. Bhd. Malaysia” which were **not accepted**. Hence, the grievance of the firm was **rejected** for Spinal Needle & Sterile Surgical Gloves and the decision of PQ evaluation committee was upheld as “**Not Prequalified**”.
Noor International	55	Spinal Needle Sterile Packs All Sizes	Not Qualified	Annual Financial turnover is less than 300 million	Not Prequalified	Copies of Goods Declaration certificates of quoted items of last three years not attached (2018, 2019); Undertaking for knockdown clause 3,6,7,8,9 and 10 not as prescribed in PQD		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Silver Surgical Complex (Pvt.) Ltd	41	I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 22G	Not Qualified	Valid ISO 13485 from PNAC Approved Body/NANDO database under the relevant European directive not attached; Product's valid CE/UNFPA/JMHLW/US FDA approval certification or prequalification by WHO not attached. Firm submitted false, fabricated, materially incorrect information on affidavit against knock down clause 10 of KNOCK	Not Prequalified	The quoted item did not comply with Quality Compliance Standards (EMA/JMHLW/US FDA/prequalified by WHO); Undertaking of "Any Spurious sample of quoted items"; Undertaking for "Any Punitive Action Taken by DRAP since (01-01-2019). (Punitive means, Prosecution launched in drug court)"; Undertaking for "Any Punitive Action Taken by PQCB since (01-01-2019). (Punitive means, Prosecution	Dear Sir, With reference to above mentioned subject, you are requested to allow us to clarify objections raised upon on our scrutiny report as per Attach evidences OBJECTIONS AGAINST PRE-QUALIFICATION [FIRM WISE] A. Valid ISO 13485 from PNAC Approved Body/NANDO database under the relevant European directive not attached; B. Product's valid CE/UNFPA/JMHLW/US FDA approval certification or prequalification by WHO not attached. C. Firm submitted false, fabricated, materially incorrect information on affidavit against knock down clause 10 of KNOCK DOWN CRITERIA (Quoted Product/Item Wise)- Manufacturer/Sole Agents-Medical Devices. Replies to objections Point Wise (FIRM WISE) Point A: We initially attached our letter of recommendation from PNAC approved body citing that certificate is in progress and will be issued in meantime. Now please find attached Valid ISO 13485 from PNAC Approved Body with this letter (Annexure A1) and the accreditation body document by PNAC (Annexure A2) Point B: Product's valid CE/UNFPA/JMHLW/US FDA approval certification or prequalification by WHO. Please note this clause has been challenged in Honorable High Court of Punjab by our lawyers as invalid and not applicable on local manufacturers. Stay Order against the finalization of bidding process with reference to this point is attached (Annexure B1) along with its writ Petition (Annexure B2). [This is not out of context to mention here that this rejection is clear violation of the honorable Lahore high court orders passed against the petition filled by Silver Surgical Complex Pvt ltd and the company reserve the right to initiate contempt proceedings in the Honorable High Court against the department.] Point C: Reply to the reason of rejection levelled by technical evaluation committee that the firm stated a wrong information through Affidavit, fact of the matter is that the Provincial quality control board Punjab Lahore had passed the order dated 30-09-2019 vide order # R-224-5/2016 and Order #340-06-2016. Both Orders were challenged in Honorable Lahore High court through writ petition no 78293/2019 and writ petition no 411/2020. Honorable Lahore High Court was pleased to suspend the both orders and issued a notice to all respondents including PQCB Punjab Lahore. (Latest Certified Copy of Order is attached as Annexure C1 /C2). Consequently, no complaint being filed in any Relevant Drug Court by any Drug inspector. This is pertinent to mention here that the petitioner company/silver surgical complex (Pvt.) ltd submitted the certified copies of the order passed by honorable Lahore High Court and got receiving from PQCB after submitting the same on 16-01-2020. Copy of that receipt is annexed for ready reference (Annexure C3). This is not out of context to mention here that this rejection is clear violation of the Honorable Lahore high court orders and the company reserve the right to initiate contempt proceedings in the Honorable High Court against the department. OBJECTIONS AGAINST PRE-QUALIFICATION [ITEM WISE] A. The quoted item did not comply with Quality Compliance Standards (EMA/JMHLW/US FDA/prequalified by WHO); B. Undertaking of "Any Spurious sample of quoted items"; C. Undertaking for "Any Punitive Action Taken by DRAP since (01-01-2019). (Punitive means, Prosecution launched in drug court)" are not as prescribed in PQD Replies to objections Point Wise (PRODUCT WISE) Point A: This point is same in spirit and term regarding international certification of product as point 2 and as such please find stay order from high court which is readily applicable on this point as well. (Annexure D1) Point B,C,D: As per published comments in prequalification report "(5) Undertaking of "Any Spurious sample of quoted items" (6) Undertaking for "Any Punitive Action Taken by DRAP since (01-01-2019). (Punitive means, Prosecution launched in drug court) (7) Undertaking for "Any Punitive Action Taken by PQCB since (01-01-2019). (Punitive means, Prosecution launched in drug court)" are not as prescribed in PQD." Now Please find attached undertakings as prescribed in PQD (Annexure E1/E2/E3) We hope to clarify all misunderstandings with above statements and request an audience, if necessary, to further discuss if any information or query seems unfulfilled. We are ready to oblige to work with Government of Punjab for provision of economical and high-quality medical devices for better of not only Public of Pakistan but also benefit the national exchequer. Best Regards Signature _____ Company Secretary Silver Surgical Complex (Pvt.) Ltd Address: C-41, Scheme-33, S.I.T.E, Super Highway Industrial Area, Karachi. Tel. 0092-21-36881432-33 / Fax.0092-21-36881834, 36881751 Mobile : 0321-8217411 E-mail: info@sscltd.com.pk / communication@sscltd.com.pk / jahanzaib@sscltd.com.pk (List of Annexures) Annex A: 1- ISO Certificate by TUV Austria (PNAC CB NO 001) 2- TUV Austria Accreditation Document by PNAC Annex B: 1- Court Stay Order WP 58412/19 2- WP 58412/19 Copy Annex C: 1- Latest Certified Copy WP 411/2020 with Stay Order 2- Latest Certified Copy WP 78293/2019 with Stay Order 3- Receiving of PQCB of WP/Stay Order Annex D: 1- Court Stay Order WP 58412/19 2- WP 58412/19 Copy Annex E: 1- Affidavit "Undertaking of "Any Spurious sample of quoted items" 2- Affidavit "Undertaking for Any Punitive Action Taken by DRAP since (01-01-2019). (Punitive means, Prosecution launched in drug court)" 3- Affidavit "Undertaking for "Any Punitive Action Taken by PQCB since (01-01-2019). (Punitive means, Prosecution launched in drug court)"	Mr. Shoukat from M/s Silver Surgical attended the meeting and presented their grievance to the grievance redressal committee. The committee heard the viewpoint of the firm which was examined in the light of Evaluation Report. The committee after due deliberation and discussion, keeping in view the required parameters in detail decided that: 1.Firm provided ISO 13485 form PNAC approved body which was accepted hence grievance of the firm was accepted to the extent of this parameter only. 2. Firm provided affidavit regarding spurious/adulterated samples of its manufacturing batches which was found as per facts hance accepted, grievance of the firm was also accepted to the extent of this parameter only. 3. Firm submitted affidavit in its bid against Knock down Clause no.1 item wise i.e. Any Punitive Action Taken by PQCB since (01-01-2019). (Punitive means, Prosecution launched in drug court). In technical evaluation the said affidavit found incorrect, misleading and was contrary to facts because PQCB, vide order PQCB/R-340-06/2016 dated 30-9-2019, ordered to prosecute in Drug Court against M/s Silver Surgical Complex (Pvt) Ltd having its registered office at Superhighway Industrial area Karachi. However, in grievance firm claimed that no prosecution could be initiated as the said matter is sub-judice before the Honorable Lahore High Court and vide Order dated 26-2-2020 in W.P no. 411/2020, the Hon'ble Lahore High Court granted interim relief in favor of M/s Silver Surgical hence grievance of the firm is accepted subject to the final decision/out come of the W.P no. 411/2020. 4. **Firm failed to submit valid Quality Compliance Standards CE/JMHLW/USFDA or prequalified by WHO to against Knock down Clause no.1 item wise i.e.** **"Quality Compliance Standards CE/JMHLW/USFDA or prequalified by WHO (Certificate). Certificates provided by the firm on its own letter head are not acceptable. CE marked by conformity assessment bodies (CABs) notified in NANDO database under the relevant European directive for medical devices of European Union will be accepted only".** **The matter is sub-judice and the Hon'ble Lahore High Court, Lahore in W.P No. 58412/2019 vide order dated 27-10-2020 ordered:** **"In the meantime, bidding process shall not be finalized by the respondents "** **However, no such injunctive order is on board which suspends the requisite clause of bidding criteria. Hence grievance of the firm rejected for this parameter.** **Keeping in view above facts the overall status remained "Not Prequalified".**
Silver Surgical Complex (Pvt.) Ltd	42	I.V Cannula with/without Injection Port with Integrated Closing Cone Sterile Pack 24G	Not Qualified	Valid ISO 13485 from PNAC Approved Body/NANDO database under the relevant European directive not attached; Product's valid CE/UNFPA/JMHLW/US FDA approval certification or prequalification by WHO not attached. Firm submitted false, fabricated, materially incorrect information on affidavit against knock down clause 10 of KNOCK	Not Prequalified	The quoted item did not comply with Quality Compliance Standards (EMA/JMHLW/US FDA/prequalified by WHO); Undertaking of "Any Spurious sample of quoted items"; Undertaking for "Any Punitive Action Taken by DRAP since (01-01-2019). (Punitive means, Prosecution launched in drug court)"; Undertaking for "Any Punitive Action Taken by PQCB since (01-01-2019). (Punitive means, Prosecution		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Silver Surgical Complex (Pvt.) Ltd	39	I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 18G	Not Qualified	Valid ISO 13485 from PNAC Approved Body/NANDO database under the relevant European directive not attached; Product's valid CE/UNFPA/JMHLW/US FDA approval certification or prequalification by WHO not attached. Firm submitted false, fabricated, materially incorrect information on affidavit against knock down clause 10 of KNOCK	Not Prequalified	The quoted item did not comply with Quality Compliance Standards (EMA/JMHLW/US FDA/prequalified by WHO); Undertaking of "Any Spurious sample of quoted items"; Undertaking for "Any Punitive Action Taken by DRAP since (01-01-2019). (Punitive means, Prosecution launched in drug court)"; Undertaking for "Any Punitive Action Taken by PQCB since (01-01-2019). (Punitive means, Prosecution		
Silver Surgical Complex (Pvt.) Ltd	40	I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 20G	Not Qualified	Valid ISO 13485 from PNAC Approved Body/NANDO database under the relevant European directive not attached; Product's valid CE/UNFPA/JMHLW/US FDA approval certification or prequalification by WHO not attached. Firm submitted false, fabricated, materially incorrect information on affidavit against knock down clause 10 of KNOCK	Not Prequalified	The quoted item did not comply with Quality Compliance Standards (EMA/JMHLW/US FDA/prequalified by WHO); Undertaking of "Any Spurious sample of quoted items"; Undertaking for "Any Punitive Action Taken by DRAP since (01-01-2019). (Punitive means, Prosecution launched in drug court)"; Undertaking for "Any Punitive Action Taken by PQCB since (01-01-2019). (Punitive means, Prosecution		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Silver Surgical Complex (Pvt.) Ltd	28	Disposable Syringe 3ml with needle. (Blister pack)	Not Qualified	Valid ISO 13485 from PNAC Approved Body/NANDO database under the relevant European directive not attached; Product's valid CE/UNFPA/JMHLW/US FDA approval certification or prequalification by WHO not attached. Firm submitted false, fabricated, materially incorrect information on affidavit against knock down clause 10 of KNOCK	Not Prequalified	The quoted item did not comply with Quality Compliance Standards (EMA/JMHLW/US FDA/prequalified by WHO); Undertaking of "Any Spurious sample of quoted items"; Undertaking for "Any Punitive Action Taken by DRAP since (01-01-2019). (Punitive means, Prosecution launched in drug court)"; Undertaking for "Any Punitive Action Taken by PQCB since (01-01-2019). (Punitive means, Prosecution		
Silver Surgical Complex (Pvt.) Ltd	30	Disposable syringe 5ml with needle. (Blister pack)	Not Qualified	Valid ISO 13485 from PNAC Approved Body/NANDO database under the relevant European directive not attached; Product's valid CE/UNFPA/JMHLW/US FDA approval certification or prequalification by WHO not attached. Firm submitted false, fabricated, materially incorrect information on affidavit against knock down clause 10 of KNOCK	Not Prequalified	The quoted item did not comply with Quality Compliance Standards (EMA/JMHLW/US FDA/prequalified by WHO); Undertaking of "Any Spurious sample of quoted items"; Undertaking for "Any Punitive Action Taken by DRAP since (01-01-2019). (Punitive means, Prosecution launched in drug court)"; Undertaking for "Any Punitive Action Taken by PQCB since (01-01-2019). (Punitive means, Prosecution		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Sind Medical Stores	28	Disposable Syringe 3ml with needle. (Blister pack)	Qualified		Not Prequalified	Clause #5 Quoted product purchase order for last three years not provided.	Sir, Dear Sir, Reference to your prequalification evaluation report of manufacturing units and sole agents of foreign principals for medical devices for 2020-21 for DGHS, P&SHD, uploaded at your website on 13-11-2020. We, Sind Medical Stores being the sole agent of US FDA Approved Surgical Sutures (manufactured by Demetech Corporation-USA) as well as US FDA Approved Disposable Syringes manufactured by (Wuxi Yushou Medical Appliances Co., Ltd., China) which are registered with DRAP, Pakistan since the year 2011 & 2009 respectively. Regarding Surgical Sutures, our following products have been disqualified being the reason that copies of Purchase Orders (clause # 5) and copies of GD's (clause # 11) are not provided. In this connection, it is requested that the required documents had submitted along with the bidding documents of sutures against serial number 226,227,228,229,232,233 & 234 at inquiry no. 8,19,16,17,50,52 & 10 while Purchase orders & Gd's were attached at annexure # 51 (a,b), 55(a,b), 53(b), 54 (b), 57(b), 59(a) 52 (b) however, we are again submitting the same for your kind consideration and perusal from original file. Moreover, regarding Disposable Syringes 3m & 50ml, it is requested you that Disposable Syringes 3ml & 50ml are being supplied in private/public market since the date of registration of which invoices & orders copies are being attached for your kind perusal while Disposable Syringes 50ml have very low demand from market so, we imported according to the market need both public & private. We hereby want to bring in your kind notice that our Disposable Syringes & Sutures both are having US FDA certification which is the supreme authority in the world and our principals have been supplying their stocks since many years in international market, however, we are submitting supporting documents of both Sutures and syringes again in your kind perusal. In the light of above given facts we hope that you will understand the status and will consider our Sutures and Disposable syringes for Prequalification.	Mr. Malik Shabeer, distributor from M/s Sind Medical Stores attended the meeting and presented their grievance to the grievance redressal committee. The committee heard the viewpoint of the firm which was examined in the light of Evaluation Report. The committee after due deliberation and discussion, keeping in view the required parameters in detail decided that: 1. Firm did not provide purchase order of disposable syringe 3cc with needle for relevant consecutive three years. Hence, firm grievance is **not accepted**. 2. Firm provided purchase order of disposable syringe 50cc with needle years but did not provide good declaration certificates for consecutive three years. Hence, firm grievance was **not accepted**. 3. Firm did not provide purchase order and good declaration certificates of black silk 2/0, 60mm straight cutting needle for relevant consecutive three years. Hence, firm grievance was **not accepted**. 4. Firm did not provide purchase orders of black silk 1, 30mm ½ circle round body needle for relevant consecutive three years. Hence, firm grievance was **not accepted**. 5. Firm provided purchase orders and good declaration certificates of catgut chromic 2/0, 30mm ½ circle round body needle for relevant consecutive three years. Hence, firm grievance was **accepted**. 6. Firm provided purchase orders of catgut chromic 1, 30mm ½ circle round body needle for relevant consecutive three years. Hence, firm grievance was **accepted**. 7. Firm did not provide purchase order of catgut chromic 1, 40mm intestinal round body needle for relevant consecutive three years. Hence, firm grievance was **not accepted**. 8. Firm provided purchase orders of polypropylene 2/0, 30mm ½ circle round body needle for relevant consecutive three years. Hence, firm grievance was **accepted**. 9. Firm did not provide good declaration certificates of polygylcolic acid 1, 40mm ½ circle round body needle for relevant consecutive three years. Hence, firm grievance was **not accepted**. Keeping in view the compliance of the requisite compulsory parameters, the grievances of the firm was **accepted** and status of the firm declared for all of its quoted items "**Prequalified**" **except** disposable syringe 3ml, 50ml, black silk size 2/0 60mm straight cutting needle, black silk size 1, 30mm ½cicle round body, catgut chromic size 1, 40mm IRB needle and polyglycolic acid size1, 40mm ½ circle round body needle .
Sind Medical Stores	30	Disposable syringe 5ml with needle. (Blister pack)	Qualified		Prequalified			
Sind Medical Stores	29	Disposable Syringe 50ml with needle. (Blister pack)	Qualified		Not Prequalified	Clause #5 Quoted product purchase order for last three years not provided. Clause #11. Quoted product GD certificate for last three year not provided.		
Sind Medical Stores	27	Disposable Syringe 20ml with needle. (Blister pack)	Qualified		Prequalified			
Sind Medical Stores	25	Disposable syringe 10ml with needle. (Blister pack)	Qualified		Prequalified			
Sind Medical Stores	24	Disposable Insulin Syringe 1ml with needle (Blister Pack)	Qualified		Prequalified			

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Sind Medical Stores	8	Black Silk ,Size 2/0,60mm straight cutting needle	Qualified		Not Prequalified	Clause #5 Quoted product purchase order for last three years not provided. Clause #11. Quoted product GD certificate for last three year not provided.		
Sind Medical Stores	19	Catgut Chromic, Size2/0 ,30mm, 1/2 Circle Round Body needle	Qualified		Not Prequalified	Clause #5 Quoted product purchase order for last three years not provided. Clause #11. Quoted product GD certificate for last three year not provided.		
Sind Medical Stores	16	Catgut Chromic, Size 1, with 40mm Intestinal RB Needle	Qualified		Not Prequalified	Clause #5 Quoted product purchase order for last three years not provided.		
Sind Medical Stores	17	Catgut Chromic, Size 1,30mm, ½ Circle RB Needle	Qualified		Not Prequalified	Clause #5 Quoted product purchase order for last three years not provided.		
Sind Medical Stores	53	Polyglactin/ Polyglycolic acid,size 2/0,30mm, 1/2 Circle Round Body needle	Qualified		Prequalified			
Sind Medical Stores	51	Poly propylene ,Size 2/0,60mm Straight Cutting needle (SCN)	Qualified		Prequalified			
Sind Medical Stores	50	Poly propylene ,Size 2/0, 30mm 1/2 circle RB Needle	Qualified		Not Prequalified	Clause #5 Quoted product purchase order for last three years not provided.		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Sind Medical Stores	52	Polyglactin/ Polyglycolic acid, Size 1,40mm.1/2 Circle Round Body needle	Qualified		Not Prequalified	Clause #11. Quoted product GD certificate for last three years not provided.		
Sind Medical Stores	10	Black Silk,Size1, 30mm, 1/2Circle round body needle	Qualified		Not Prequalified	Clause #5 Quoted product purchase order for last three years not provided.		
Sind Medical Stores	49	Poly propylene Size 1, 40mm 1/2 circle RB Needle	Qualified		Prequalified			
Sy'ah Impex	43	I.V. Sets Sterile blister Pack	Qualified		Not Prequalified	DRC EXPIRED	As per evaluation report of Pre-Qualification of Medical devices Published on 13-11-2020, We Sy'ah Impex had been declared “Not-Prequalified item wise” Technical evaluation team mentioned that our firm is not pre-Qualified due to the following Item wise reasons. Sr # Inquiry No Generic Result Firm Wise Reasons Of Rejection Status Item wise Reason of Rejection Supporting documents Annexure 239 43 I.V. Sets Sterile blister Pack Qualified Not Prequalified DRC EXPIRED Drug registration Certificate DRAP(2009) Renewal application 2014 Bank Challan 2014 Renewal Application 2019 Bank Challan 2019 A 241 3 Auto Disable (AD)/reuse prevention (RUP) Syringe 2/3ml with needle (Blister Pack) Qualified Not Prequalified DRC expired. Quoted product is not tried and tested in local environment for at least three years; Goods Declaration certificates of quoted items of last three years not attached Drug registration Certificate DRAP 2010 Renewal application 2014 Bank Challan 2014 Renewal Application 2019 Bank Challan 2019 Past Performance last 3 years Good Declaration Certificate. 2017,2018, 2020 B 242 31 Disposable Syringe 60ml with Central Nozzle or Catheter Tip (Blister Pack) Qualified Not Prequalified DRC EXPIRED Drug registration Certificate DRAP 2009 Renewal application 2014 Bank Challan 2014 Renewal application 2019 Bank Callan 2019 C 243 28 Disposable Syringe 3ml with needle. (Blister pack) Qualified Not Prequalified DRC EXPIRED 244 29 Disposable Syringe 50ml with needle. (Blister pack) Qualified Not Prequalified DRC EXPIRED 245 30 Disposable syringe 5ml with needle. (Blister pack) Qualified Not Prequalified DRC EXPIRED Quoted product is not tried and tested in local environment for at least three years; Goods Declaration certificates of quoted items of last three years not attached Drug registration certificate DRAP 2009 Renewal application 2014 Bank Challan receipt2014 Renewal Application 2019 Bank Challan 2019 Past performance last 3years Good Declaration Certificate 2017,2018,2019,2020 D 246 26 Disposable Syringe 1ml with needle (Blister Pack) Qualified Not Prequalified DRC EXPIRED Drug registration Certificate DRAP 2009 Renewal application 2014 Bank Challan Receipt Renewal application 2019 Bank Challan receipts E 247 27 Disposable Syringe 20ml with needle. (Blister pack) Qualified Not Prequalified DRC EXPIRED 248 5 Auto Disable (AD)/reuse prevention (RUP) Syringe 5ml with needle (Blister Pack) Qualified Not Prequalified DRC expired Quoted product is not tried and tested in local environment for at least three years; Goods Declaration certificates of quoted items of last three years not attached Drug registration Certificate DRAP 2010 Renewal application 2014 Bank Challan 2014 Renewal Application 2019 Bank challan 2019 Past Performance last 3 years Good Declaration Certificate. 2017,2018, 2019 2020 F 249 25 Disposable syringe 10ml with needle. (Blister pack) Qualified Not Prequalified DRC expired clause 5 PO of 2018 not provided. Drug registration Certificate DRAP 2009 Renewal application 2014 Bank Challan Receipt 2014 Renewal application 2019 Bank Challan 2019 PO 2018 G 250 24 Disposable Insulin Syringe 1ml with needle (Blister Pack) Qualified Not Prequalified DRC EXPIRED Drug registration Certificate DRAP 2009 Renewal application 2014 Bank Challan Receipt 2014 Renewal application 2019 Bank Challan 2019 H 251 40 I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 20G Qualified Not Prequalified DRC EXPIRED Quoted product is not tried and tested in local environment for at least three years; Goods Declaration certificates of quoted items of last three years not attached Drug Registration Certificate DRAP 2014	Mr Jahangir Ahmed, Bussiness Developement Manager, from M/s SY'AH Impex (Pvt) Ltd. attended the meeting and presented their grievance to the grievance redressal committee. The committee heard the viewpoint of the firm which was examined in the light of Evaluation Report. The committee after due deliberation and discussion, keeping in view the required parameters in detail decided that : 1. The firm provided valid DRC for all quoted items **except** Urine bags sterile and sterile surgical glove 2. The firm provided PO of Auto Disable syringe 3ml with needle for relevant three years.The firm provided GD for relevant three years which was **accepted**. 3. The firm provided PO and GD of disposable syringe 5ml with needle for relevant three years which was **accepted**. 4. The firm provided PO and GD of Auto Disable syringe 5ml with needle for relevant three years which was **accepted**. 5. The firm provided PO of disposable syringe 10 ml with needle for relevant three years which was **accepted**. 6. The firm did not provide PO and GD of I.V cannula with injection port and integrated closing cone sterile pack 20G,18G,24G and 22G which was **not accepted**. 7. The firm did not provided PO of sterile surgical gloves pairs 6 1/2 7, 71/2 which was **not accepted**. 8. The firm did not provide CE certificate of Volumetric Chamber 100ml. Hence status of the item remained "**Not Prequalified**". Keeping in view the compliance of the requisite compulsory parameters, the grievances of the firm was accepted.Hence the status of firm declared **"Prequalified"** for all quoted items **except** Urine bag; Sterile surgical gloves; IV Cannula with Injection Port and Integrated Closing Cone 18G, 20G, 22G & 24G; and Volumetric Chamber 100ml.
Sy'ah Impex	64	Volumetric Chamber (I.V Burette) Sterile Packs 100ml size	Qualified		Not Prequalified	DRC EXPIRED		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Sy'ah Impex	3	Auto Disable (AD)/re-use prevention (RUP) Syringe 2/3ml with needle (Blister Pack)	Qualified		Not Prequalified	DRC expired. Quoted product is not tried and tested in local environment for at least three years; Goods Declaration certificates of quoted items of last three years not attached	Renewal Application 2019 Bank Challan Receipts 2019 Past Performance last 3 years Goods Declaration Certificate 2016,2017,2018,2019 I 252 39 I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 18G Qualified Not Prequalified DRC EXPIRED Quoted product is not tried and tested in local environment for at least three years; Goods Declaration certificates of quoted items of last three years not attached 253 42 I.V Cannula with/without Injection Port with Integrated Closing Cone Sterile Pack 24G Qualified Not Prequalified DRC EXPIRED Quoted product is not tried and tested in local environment for at least three years; Goods Declaration certificates of quoted items of last three years not attached 254 41 I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 22G Qualified Not Prequalified DRC EXPIRED Quoted product is not tried and tested in local environment for at least three years; Goods Declaration certificates of quoted items of last three years not attached 255 63 Urine Bags Sterile (2000ml) Packs Qualified Not Prequalified DRC EXPIRED Application for registration after Exemption period (Medical Devices rule) Bank Challan receipt J 256 56 Sterile Surgical Gloves Pairs 6 ½, 7, 7 ½ (Powdered) Qualified Not Prequalified DRC not provided. CLAUSE 5 Quoted product is not tried and tested in local environment for at least three years. Application for registration.2020 Bank challan 2020 Goods Declaration certificate 2017,2018,2019 K We regret for our negligence and thanks you for giving us an opportunity to provide the missing documents. Sir, Sy'ah was founded in 1993 to primarily introduce hygienic products in Pakistan. Since hygiene in healthcare establishments is one of the most overlooked areas in the country, there was dire need to fulfill the basic health needs of people of different age groups. Our diversified healthcare devices make us an integral part of the lives of millions of people across the country. Not only the company took the initiative of launching advanced products for enhanced health care system it has also created a milestone by creating new markets that did not exist earlier in Pakistan – a tradition that is continued and celebrated until today.	
Sy'ah Impex	31	Disposable Syringe 60ml with Central Nozzle or Catheter Tip (Blister Pack)	Qualified		Not Prequalified	DRC EXPIRED		
Sy'ah Impex	28	Disposable Syringe 3ml with needle. (Blister pack)	Qualified		Not Prequalified	DRC EXPIRED		
Sy'ah Impex	29	Disposable Syringe 50ml with needle. (Blister pack)	Qualified		Not Prequalified	DRC EXPIRED		
Sy'ah Impex	30	Disposable syringe 5ml with needle. (Blister pack)	Qualified		Not Prequalified	DRC EXPIRED Quoted product is not tried and tested in local environment for at least three years; Goods Declaration certificates of quoted items of last three years not attached		
Sy'ah Impex	26	Disposable Syringe 1ml with needle (Blister Pack)	Qualified		Not Prequalified	DRC EXPIRED		
Sy'ah Impex	27	Disposable Syringe 20ml with needle. (Blister pack)	Qualified		Not Prequalified	DRC EXPIRED		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Sy'ah Impex	5	Auto Disable (AD)/re-use preventio n (RUP) Syringe 5ml with needle (Blister Pack)	Qualified		Not Prequalified	DRC expired Quoted product is not tried and tested in local environment for at least three years; Goods Declaration certificates of quoted items of last three years not attached		
Sy'ah Impex	25	Disposabl e syringe 10ml with needle. (Blister pack)	Qualified		Not Prequalified	DRC expired clause 5 PO of 2018 not provided.		
Sy'ah Impex	24	Disposabl e Insulin Syringe 1ml with needle (Blister Pack)	Qualified		Not Prequalified	DRC EXPIRED		
Sy'ah Impex	40	I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 20G	Qualified		Not Prequalified	DRC EXPIRED Quoted product is not tried and tested in local environment for at least three years; Goods Declaration certificates of quoted items of last three years not attached		
Sy'ah Impex	39	I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 18G	Qualified		Not Prequalified	DRC EXPIREDQuoted product is not tried and tested in local environment for at least three years; Goods Declaration certificates of quoted items of last three years not attached		
Sy'ah Impex	42	I.V Cannula with/witho ut Injection Port with Integrated Closing Cone Sterile Pack 24G	Qualified		Not Prequalified	DRC EXPIRED Quoted product is not tried and tested in local environment for at least three years; Goods Declaration certificates of quoted items of last three years not attached		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Sy'ah Impex	41	I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 22G	Qualified		Not Prequalified	DRC EXPIRED Quoted product is not tried and tested in local environment for at least three years; Goods Declaration certificates of quoted items of last three years not attached		
Sy'ah Impex	63	Urine Bags Sterile (2000ml) Packs	Qualified		Not Prequalified	DRC EXPIRED		
Sy'ah Impex	56	Sterile Surgical Gloves Pairs 6 ½, 7, 7 ½ (Powdered)	Qualified		Not Prequalified	DRC not provided. CLAUSE 5 Quoted product is not tried and tested in local environment for at least three years.		
The Searle Company Limited	56	Sterile Surgical Gloves Pairs 6 ½, 7, 7 ½ (Powdered)	Not Qualified	Clause 3:Undertaking not legalized/notarized, Clause 4:Not legalized/notarized Clause 9:Not legalized/notarized and address of storage facility not mentioned on undertaking, Clause 10:Not legalized/notarized, Clause 12:chamber of commerce from country of manufacture is inappropriate for Abu Dhabi Medical Devices Co. LLC Clause 15:Non	Not Prequalified	Clause 3, 6, 7, 8, 9, 10: Not legalized / notarized	It is stated with all due respect to your honorable chairman grievance committee that as per Evaluation report of Pre – qualification of medical devices dated 13-11-2020. We M/S The Searle Company Limited had been declared Not Pre qualified as firm wise as well as item wise. Your Honorable Evaluation team mentioned that our firm is not Pre qualified due to following reasons: FIRM WISE KNOCK DOWN; 1. Undertaking not Legalized / Notarized: Sir, we are presenting valid Legalized / Notarized under takings as per firm wise knock down clauses No. 3, 4, 9, 10, 15, 17 and 19 for your kind consideration. We had corrected the statement of affidavit of clause No.15 & 17 as per specification about which Evaluation team raised an objection in Evaluation report. All above discussed undertakings are attached for your kind perusal. 2. Inappropriate chamber of commerce from country of manufacturer (ADMD): Sir in this regard we already submitted manufacturer's chamber of commerce registration from country of manufacturer and we are submitting the same document for your kind consideration along with other supportive documents of manufacturer issued by different international quality assurance agencies and national authorities of manufacturer's country. These documents are as below: a. CE CERTIFICATE OF MANUFACTURER (NOTARIZED / LEGALIZED) b. FREE SALES CERTIFICATE OF MANUFACTURER (NOTARIZED / LEGALIZED) c. MANUFACTURING LICENSE. d. ISO 9001 & ISO 14001. 3. Non – Compliance due to firm wise knockdown clause no 15: (Case no P- 293 - 3 / 2019 declared Byscard substandard and adulterated by DTL LHR). As per specification of clause no. 15 of PQ documents "None of its MANUFACTURED batch sample has been declared substandard or adulterated since 2017." Sir, we M/S the Searle Company Limited applied in this particular Prequalification as "Sole Agent of Foreign Principal of Medical Device." Our products MEDECO I.V Cannula and Protiex Surgical and Examination Gloves are being manufactured by Abu Dhabi Medical Devices Co. LLC, UAE and TG Medical, Malaysia respectively under stringent quality control and assurance process. This is why none of our supplied batch of our quoted product declared adulterated / Substandard since 2017. Sir, the specification of clause no. 15 of firm wise knock down criteria exhibits to locally manufactured batch samples. Whereas our case is different, in business of Medical Devices we M/S The Searle Company Limited import our quoted product in finished and packed form from our principals and store in our warehouse as per recommendation of the manufacturer at required temperature and follows good storage & distribution practices. Furthermore, there is departmental segregation for local & imported product's businesses. Head of the company is same but divisional heads for "Locally Manufactured Medicine" and "Imported Medical Devices" are	Mr. Ahmad Iqbal, Regional Manegar from M/s The Searle Company Limited attended the meeting and presented their grievance to the grievance redressal committee. The committee heard the view point of the representative of the firm which was examined in the light of Evaluation Report. The committee after due deliberation and discussion, keeping in view the required parameters in detail, decided that: 1. The firm submitted the affidavits for clause 3,4,9,10,17,19 of firm wise knock down criteria and was **accepted**. 2. The firm grievance regarding clause 12 of the firm wise knock down criteria was **rejected** as the certificate was for import only and not for manufacturers. 3. The firm did not submitted any documentary evidence for its adultrated batches in compliance too the clause 15 of firm wise knock down criteria, hence the grievance of the firm was **rejected**. 4. The submitted affidavit for Clause 3,6,7,8,9 and 10 of item wise knock down criteria was **accepted**. 5. The firm attached required product experience for Item No. 39 (I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 18G), 40 (I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 20G), 41 (I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 22G) and 42 (I.V Cannula with/without Injection Port with Integrated Closing Cone Sterile Pack 24G) and was **accepted**. 6. The firm attached required product GDs for Item No. 30 (Disposable Syringe 5ml with needle. (Blister pack)), 39 (I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 18G), 40 (I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 20G), 41 (I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 22G) and 42 (I.V Cannula with/without Injection Port with Integrated Closing Cone Sterile Pack 24G) and was **accepted**. 7. The firm did not submitted the documentary evidence in compliance to clause 5 of item wise knock down criteria for Item No. 1 (Auto Disable (AD)/re-use prevention (RUP) Syringe 0.5ml with needle (Blister Pack)), 24 (Disposable Insulin Syringe 1ml with needle (Blister Pack)), 28 (Disposable Syringe 3ml with needle. (Blister pack)) and 30 (Disposable Syringe 5ml with needle. (Blister pack)). Hence the grievance of the firm was rejected. 8. The firm did not submitted the documentary evidence in compliance to clause 11 of item wise knock don criteria for Item No. 1 (Auto Disable (AD)/re-use prevention (RUP) Syringe 0.5ml with needle (Blister Pack)), 24 (Disposable Insulin Syringe 1ml with needle (Blister Pack)), 28 (Disposable Syringe 3ml with needle. (Blister pack)). Hence the grievance of the firm was rejected. Keeping in view the non-compliance of the requisite compulsory parameters, the grievances of the firm was

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
The Searle Company Limited	34	Examination Gloves Latex (S.M.L)	Not Qualified	Clause 3:Undertaking not legalized/notarized, Clause 4:Not legalized/notarized Clause 9:Not legalized/notarized and address of storage facility not mentioned on undertaking, Clause 10:Not legalized/notarized, Clause 12:chamber of commerce from country of manufacture is inappropriate for Abu Dhabi Medical Devices Co. LLC Clause 15:Non	Not Prequalified	Clause 3, 6, 7, 8, 9, 10: Not legalized / notarized	different. We applied in prequalification of Imported medical devices which are not being manufactured in local plants. On the basis of above fact and status we would pleaded to your kindness to may please accept our grievances and consider us as an importer not manufacturer. ITEM WISE KNOCK DOWN; Legalized / Notarized undertaking: Legalized / Notarized undertakings of knock down clauses no. 3, 6, 7, 8, 9 and 10 are attached for your kind consideration. GOODS DECLARATION: As per clause no.11 GD of 2019 of our quoted product is again submitted for your kind consideration. Market Experience: As per clause no. 05 Experience of 2018 is also attached along with for your kind perusal. SIR, IN THE LIGHT OF ABOVE MENTIONED FACTS AND CURRENT STATUS OF OUR FIRM WE HOPE THAT YOUR HONORABLE CHAIRMAN OF GRIEVANCES COMMITTEE CERTAINLY CONSIDER OUR SOLICITATION AND DECLARED OUR FIRM AND PRODUCTS PREQUALIFIED IN PRE – QUALIFICATION OF FOREIGN PRINCIPAL OF MEDICAL DEVICES. BEST REGARDS, THE SEARLE COMPANY	**rejected** and upheld the decision of prequalification evaluation committee and status of the firm is still declared as "**Not Prequalified**"
The Searle Company Limited	42	I.V Cannula with/without Injection Port with Integrated Closing Cone Sterile Pack 24G	Not Qualified	Clause 3:Undertaking not legalized/notarized, Clause 4:Not legalized/notarized Clause 9:Not legalized/notarized and address of storage facility not mentioned on undertaking, Clause 10:Not legalized/notarized, Clause 12:chamber of commerce from country of manufacture is inappropriate for Abu Dhabi Medical Devices Co. LLC Clause 15:Non	Not Prequalified	Clause 3, 6, 7, 8, 9, 10: Not legalized / notarized Clause 11: GD for 2019 not attached. Clause 5:experience for year 2018 not attached		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
The Searle Company Limited	41	I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 22G	Not Qualified	Clause 3:Undertaking not legalized/notarized, Clause 4:Not legalized/notarized Clause 9:Not legalized/notarized and address of storage facility not mentioned on undertaking, Clause 10:Not legalized/notarized, Clause 12:chamber of commerce from country of manufacture is inappropriate for Abu Dhabi Medical Devices Co. LLC Clause 15:Non	Not Prequalified	Clause 3, 6, 7, 8, 9, 10: Not legalized / notarized Clause 11: GD for 2018 and 2019 not attached. Clause 5:experience for year 2018 not attached		
The Searle Company Limited	39	I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 18G	Not Qualified	Clause 3:Undertaking not legalized/notarized, Clause 4:Not legalized/notarized Clause 9:Not legalized/notarized and address of storage facility not mentioned on undertaking, Clause 10:Not legalized/notarized, Clause 12:chamber of commerce from country of manufacture is inappropriate for Abu Dhabi Medical Devices Co. LLC Clause 15:Non	Not Prequalified	Clause 3, 6, 7, 8, 9, 10: Not legalized / notarized Clause 11: GD for 2019 not attached. Clause 5:experience for year 2018 not attached		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
The Searle Company Limited	40	I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 20G	Not Qualified	Clause 3:Undertaking not legalized/notarized, Clause 4:Not legalized/notarized Clause 9:Not legalized/notarized and address of storage facility not mentioned on undertaking, Clause 10:Not legalized/notarized, Clause 12:chamber of commerce from country of manufacture is inappropriate for Abu Dhabi Medical Devices Co. LLC Clause 15:Non	Not Prequalified	Clause 3, 6, 7, 8, 9, 10: Not legalized / notarized Clause 11: GD for 2019 not attached. Clause 5:experience for year 2018 not attached		
The Searle Company Limited	1	Auto Disable (AD)/re-use prevention (RUP) Syringe 0.5ml with needle (Blister Pack)	Not Qualified	Clause 3:Undertaking not legalized/notarized, Clause 4:Not legalized/notarized Clause 9:Not legalized/notarized and address of storage facility not mentioned on undertaking, Clause 10:Not legalized/notarized, Clause 12:chamber of commerce from country of manufacture is inappropriate for Abu Dhabi Medical Devices Co. LLC Clause 15:Non	Not Prequalified	Clause 3, 6, 7, 8, 9, 10: Not legalized / notarized Clause 5: PO for 2018 and 2019 not attached. Clause 11: GD for 2018 and 2019 not attached.		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
The Searle Company Limited	24	Disposable Insulin Syringe 1ml with needle (Blister Pack)	Not Qualified	Clause 3:Undertaking not legalized/notarized, Clause 4:Not legalized/notarized Clause 9:Not legalized/notarized and address of storage facility not mentioned on undertaking, Clause 10:Not legalized/notarized, Clause 12:chamber of commerce from country of manufacture is inappropriate for Abu Dhabi Medical Devices Co. LLC Clause 15:Non	Not Prequalified	Clause 3, 6, 7, 8, 9, 10: Not legalized / notarized Clause 5: PO for 2018 and 2019 not attached. Clause 11: GD for 2019 not attached.		
The Searle Company Limited	28	Disposable Syringe 3ml with needle. (Blister pack)	Not Qualified	Clause 3:Undertaking not legalized/notarized, Clause 4:Not legalized/notarized Clause 9:Not legalized/notarized and address of storage facility not mentioned on undertaking, Clause 10:Not legalized/notarized, Clause 12:chamber of commerce from country of manufacture is inappropriate for Abu Dhabi Medical Devices Co. LLC Clause 15:Non	Not Prequalified	Clause 3, 6, 7, 8, 9, 10: Not legalized / notarized Clause 5: PO for 2018 and 2019 not attached. Clause 11: GD for 2018 and 2019 not attached.		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
The Searle Company Limited	30	Disposable syringe 5ml with needle. (Blister pack)	Not Qualified	Clause 3:Undertaking not legalized/notarized, Clause 4:Not legalized/notarized Clause 9:Not legalized/notarized and address of storage facility not mentioned on undertaking, Clause 10:Not legalized/notarized, Clause 12:chamber of commerce from country of manufacture is inappropriate for Abu Dhabi Medical Devices Co. LLC Clause 15:Non	Not Prequalified	Clause 3, 6, 7, 8, 9, 10: Not legalized / notarized Clause: PO for 2018 and 2019 not attached. Clause 11: GD for 2019 not attached.		
Total Technologies (Pvt.) Limited	60	Surface Disinfectant Solution Of appropriate composition	Not Qualified	Expired DSL; Minimum financial turnover is less than Rs.300 Million	Not Prequalified	Valid DRC/ Device Enlistment certificate not attached; Quoted product is not tried and tested in local environment for at least three years (2017); Copies of Goods Declaration certificates of quoted items of last three years not attached	Sir, Kindly find the attached file of Grievance Application with required documents of Medical Device for your kind perusal Thank you!	Mr. Muhammad Kashif, Sales Manager, from M/s Total Technologies (Pvt) Ltd. attended the meeting and presented their grievance to the grievance redressal committee. The committee heard the view point of the representative of the firm which was examined in the light of Evaluation Report. The committee after due deliberation and discussion, keeping in view the evaluation criteria decided that: 1. The firm provided copy of renewal application for DSL, which was **accepted**. 2. The firm provided copy of POs for Instrumental Disinfectant Solution & Surface Disinfectant Solution, which were **accepted**. 2. The firm did not provide Valid DRC/ Device Enlistment certificate of the quoted item. 3. The firm provided bank statements of FY 2019-20 till Nov 2020. However the firm did not provide FBR Income/Sales Tax Return of FY 2019-20 to establish that its financial turnover is more that Rs. 300 Million. Hence, the grievance of the firm was **rejected** to the extent of this parameter and the decision of PQ evaluation committee was upheld as "**Not Prequalified**". 4. The firm did not provide copies of GDs of last three years consecutively. Hence, the grievance of the firm was **rejected** to the extent of this parameter and the decision of PQ evaluation committee was upheld as "**Not Prequalified**".
Total Technologies (Pvt.) Limited	44	Instrumental Disinfectant Solution Of appropriate composition	Not Qualified	Expired DSL; Minimum financial turnover is less than Rs.300 Million	Not Prequalified	Valid DRC/ Device Enlistment certificate not attached; Quoted product is not tried and tested in local environment for at least three years (2017); Copies of Goods Declaration certificates of quoted items of last three years not attached		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
UDL Distribution Private Limited	20	CVP Line (Double Lumen) (All Sizes)	Not Qualified	clause 19. no undertaking on affidavit is provided. clause 15. only quoted items are declared that those are not suporious/ adultrated	Not Prequalified		Dear Sir, This is in reference to the evaluationn report of prequalification of firms 2020-21, we bring to your kind notice that as per our understanding the documents attached in our submitted bid. We request your good self to kindly review the subject grievannce and give us chance to serve you the quality products. Best Regards	Mr. Amir Mahmood Khan from M/s UDL Distribution (Pvt) Ltd. attended the meeting and presented their grievance to the grievance redressal committee. The committee heard the view point of the representative of the firm which was examined in the light of Evaluation Report. The committee after due deliberation and discussion, keeping in view the evaluation criteria decided that: The firm provided undertaking against firm-wise knockdown clause no. 15 & 19, which were **accepted**. The firm provided copies of GDs for the quoted item of last three years consecutively, which were **accepted**. Hence grievance of the firm was **accepted** and the status of the firm declared "**Prequalified**" for all quoted items.
UDL Distribution Private Limited	21	CVP Line (Double Lumen) (For Dialysis)	Not Qualified	clause 19. no undertaking on affidavit is provided. clause 15. only quoted items are declared that those are not suporious/ adultrated	Not Prequalified	GD Certificate not provided for last three years		
UNISA (Pvt) Limited	43	I.V. Sets Sterile blister Pack	Not Qualified	CE Certificate is not issued from EU NB under the relevant European directive for medical devices of European Union; Undertaking of "none of its manufactured batch sample has been declared Spurious/Adulterated since 2017 onward" since last two years	Not Prequalified	CE Certificate is not issued from EU NB under the relevant European directive for medical devices of European Union; Quoted product is not tried and tested in local environment for at least three years; Undertaking of "Any Spurious sample of quoted items" not attached.Declared substandard bt DTL BWP vide No.P-554-6/2019,No.P-558-6/2019,No.P-585-6/2019,and DTL LHR Vide No.P-136-2/2020.	Sir, Ref: UPL/PRE-QCTN/2020-2021/1 Dated 21st-NOV-2020 TO, Director General Health, Primary & Secondary Health Care Department, DGHS, Punjab 24-Cooper Road. Lahore Subject: Grievances for Redressal 1- CE certificate is not from EU NUB 2- Market experience less than three years 3- Undertaking of any spurious samples 4- Substandard batch DTL 1- CE certificate is not from EU NUB In this regards we submit that, CE certificate was attached with the pre-qualification documents and submitted online through portal. The CE certificate attached is issued from American notified body which can be online verified through their website. The CE certificate of American body has the same guidelines and production protocol as of European notified body, hence, both certificates hold the same quality standards and meets the same requirements. Needless to mention that, CE certificate is a third body assessment, while, in the pre-qualification documents cGMP certificate is submitted. A cGMP certificate is issued to any firm after physical inspection of the company by executive board members of DRAP. After assessing standard manufacturing practices followed by the company cGMP is issued to appreciate quality manufacturing nationally and enable procuring agencies nationally and internationally to procure with confidence that procuring products will be of high quality and standards. UNISA PVT LTD is leading manufacturing company of Disposable syringes, IVSET and various other medical devices, supplied to various government institutions like GOVT OF KPK, GOVT OF BALOCHISTAN, GOVT OF PUNJAB, DGP Army, PIMS Islamabad and now huge demand from private reputable hospitals like Shifa international Islamabad, Quaid-e-azam Islamabad and other well-known hospitals. All the products manufactured are of high quality with timely supplies. CE certificate from an European notified body, we believe is non-justifiable for pre-qualification of local manufacturers and may be a reason to pave way for multinational companies costing national economy millions of dollars by eliminating competitive bidding among suppliers. Providing such unanimous opportunities to a single bidder is also violation of PEPRA rules as well. But rather to suggest that CE is demand for import in Europe and cGMP is basic standard in Pakistan. 2- Market Experience less than three years: In this regards we submit that, license to UNISA PVT LTD was issued in AUG, 2018. A total of experience of 28 months is already passed with a very positive response and good will. To pre-qualify an experience of 36 months has been made mandatory. It is to request that, the items quoted are disposable medical devices, which has no active pharmaceutical ingredient. Three years market experience shall be mandatory for medicines not medical devices, as	Mr. Zeeshan from M/s UNISA Private Ltd. attended the meeting and presented their grievance to the grievance redressal committee. The committee heard the viewpoint of the firm which was examined in the light of Evaluation Report. The committee after due deliberation and discussion, keeping in view the required parameters in detail decided that: 1. Firm submitted undertaking regarding spurious/adulterated samples of its manufactured batches against knock down clause no 15 which was found correct and accepted hance grievance of the firm was **accepted** to the extent of this clause only. 2. Firm failed to provide any evidence regarding 3 years experience of its quoted items. Hence grievance of the firm was **rejected** for this parameter. 3. Firm submitted data of its sampled batches and it was calculated that firm failed sample batches of its quoted I.V set is more than 5% hence grievance of the firm was **rejected** in this regard only. 4. As per knock down criteria of Prequalification CE certificate must be from notified bodies of CE marked by conformity assessment bodies (CABs) notified in NANDO database under the relevant European directive for medical devices of European Union will be accepted only. However, submitted by M/s Unisa PVT Ltd CE certificate No. MVC 601776115/20/AE Dated 29th January 2020 issued by Mega Vision International LLC is seemed to be fake and not verifiable from conformity assessment bodies (CABs) notified in NANDO database (Which are only authorized bodies to issue CE certificates under European Directive 93/42/ECC). It is pertinent to mention hare that the identical CE certificate No. MVC 447213215/19/AE Dated 30th January 2019 also issued by Mega Vision International LLC, to M/s Unisa (PVT) Ltd. was sent to European commission for verification through an email European commission declared that certificate unauthenticated in its reply which was retreated as "To our knowledge, this does not look an authentic certificate issued under the current European Medical Directive 93/42/EEC by a designated notified body. As you will note, there is no notified body number on the certificate. The list of notified bodies designated under the MDD 93/42/EEC can be found in NANDO."(Annex-B) The act of the firm is serious violation of terms and conditions of prequalification documents and falls under the category of corrupt and fraudulent practices as defined under Rule-21 of the Punjab Procurement Rules 2014. Keeping in view of above facts, grievance of the firm was rejected & the overall status remained "**Not Prequalified**".

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
UNISA (Pvt) Limited	25	Disposable syringe 10ml with needle. (Blister pack)	Not Qualified	CE Certificate is not issued from EU NB under the relevant European directive for medical devices of European Union; Undertaking of "none of its manufactured batch sample has been declared Spurious/Adulterated since 2017 onward" since last two years	Not Prequalified	CE Certificate is not issued from EU NB under the relevant European directive for medical devices of European Union; Quoted product is not tried and tested in local environment for at least three years; Undertaking of "Any Spurious sample of quoted items" not attached	stability studies of medicines is much important than of a disposable medical device. However it is worthy to mention that, during the period of 28 months we have supplied to various government institutions mentioned earlier, across the country with high reputation and quality products supplied in millions of pieces and hundreds of batches, all stands clear except one which is justified and discussed in details in this letter. In a very short period of time, UNISA PVT LTD has emerged tremendously with highest quality in DMDs in Pakistan and has surpassed all those local manufacturers having decades of experience. It is worth mentioning that among various importers one of them has completely stopped operation and is replaced by quality production and supplies by UNISA in DMD's Marking three years mandatory market experience for disposable medical devices is also a violation of PEPRA rules, where, competitive bidding has been compromised to pave way for few bidders by market experience and among those few bidders then paving way for multinational bidders by CE from EU NBM. Needless to mention that, among all bidding documents of all other government institution issued for technical qualification has no such mandatory clause of three years. 3- UNDER TAKING OF ANY SPURIOUS SAMPLES: In this regard we submit that, an undertaking of none of spurious samples was attached and submitted online through portal, but, may be missed to find. With this letter please find attached undertaking for kind perusal and record. 4- Declared substandard batches: For item no 43 it has been objected that supply of quoted item is declared sub-standard by DTL BWP for which we submit that, the two samples collected were tested for sterility among which one was passed, while, another one was turbid. The matter of this batch is already in judicial proceeding with honorable High court of Lahore, where the decision of DTL has been challenged. As the same batch has been declared pass at another DTL of Faisalabad and even among two samples one is pass and another shows turbidity in DTL BWP, which, according to USP/BP and we quote "if a sample is turbid it shall be further tested and may be due to reason of contamination due to mishandling at laboratory". The decision is challenged for the reason that, the dispatch was done after assurance of sterility in the quarantine period, the same batch dispatched to various stations where it stands sterile and clear, while, only in DTL BWP its half sterile/half not. The picture is completely doubtful and affirms the USP/BP reason of turbidity, as growth was not seen and the solution was turbid only. However, it is important to highlight the matter that, the batch objected are two among 236 batches supplied since 1-1-2019 to various government institutes. Composing of a total 0.84 percent of failure, which, justify the undertaking already submitted at your end, that, the company has less than 5% batches failed or declared sub-standard. The lists of batches are given in the table below with stations and can be verified from the purchase orders attached as well. SR No PRODUCT BATCH NO SUPPLIED TO 1. IV-Set 190103 Govt. of Punjab 2. IV-Set 190104 Govt. of Punjab 3. IV-Set 190114 DHQ Sahiwal 4. IV-Set 190116 DHQ Sahiwal 5. IV-Set 190124 DHA Jhelum 6. IV-Set 190125 Govt. of Punjab 7. IV-Set 190201 Govt. of Punjab 8. IV-Set 190202 Govt. of Punjab 9. IV-Set 190203 Govt. of Punjab 10. IV-Set 190204 Govt. of Punjab 11. IV-Set 190205 Govt. of Punjab 12. IV-Set 190207 Bahawalpur Govt. 13. IV-Set 190208 Bahawalpur Govt. 14. IV-Set 190209 Bahawalpur Govt. 15. IV-Set 190220 Govt. of Punjab 16. IV-Set 190221 Govt. of Punjab 17. IV-Set 190222 Govt. of Punjab 18. IV-Set 190301 PIMS Islamabad 19. IV-Set 190302 MERF 20. IV-Set 190312 B. Braun 21. IV-Set 190313 B. Braun 22. IV-Set 190314 B. Braun 23. IV-Set 190315 Pakpattan Govt. 24. IV-Set 190321 Nankana 25. IV-Set 190322 Nankana 26. IV-Set 190323 Jhelum Govt. 27. IV-Set 190324 Jhelum Govt. 28. IV-Set 190402 PIMS Islamabad 29. IV-Set 190403 Govt. of Punjab 30. IV-Set 190404 Govt. of Punjab 31. IV-Set 190405 Govt. of Punjab 32. IV-Set 190406 Govt. of Punjab 33. IV-Set 190407 Govt. of Punjab 34. IV-Set 190408 Govt. of Punjab 35. IV-Set 190410 Govt. of Punjab 36. IV-Set 190411 Govt. of Punjab 37. IV-Set 190423 Govt. of Punjab 38. IV-Set 190424 Govt. of Punjab 39. IV-Set 190425 Govt. of Punjab 40. IV-Set 190426 Govt. of Punjab 41. IV-Set 190427 Govt. of Punjab 42. IV-Set 190428 Govt. of Punjab 43. IV-Set 190429 MTI LRH 44. IV-Set 190430 MTI LRH 45. IV-Set 190431 MTI LRH 46. IV-Set 190509 Govt. of Punjab 47. IV-Set 190501 Govt. of Punjab 48. IV-Set 190517 Govt of Sindh 49. IV-Set 190519 Govt of Punjab 50. IV-Set 190520 Govt. of Punjab 51. IV-Set 190512 RYK Govt. 52. IV-Set 190522 PIMS Islamabad 53. IV-Set 190523 PIMS Islamabad 54. IV-Set 190524 PIMS Islamabad 55. IV-Set 190510 Govt. of Punjab 56. IV-Set 190511 Govt. of Punjab 57. IV-Set 190507 Govt. of Punjab 58. IV-Set 190508 Govt. of Punjab 59. IV-Set 190603 Govt. of Punjab 60. IV-Set 190622 MTI LRH 61. IV-Set 190623 MTI LRH 62. IV-Set 190624 MTI LRH 63. IV-Set 190625 MTI LRH 64. IV-Set 190626 MTI LRH 65. IV-Set 190801 Pak Defence Force 66. IV-Set 190802 CMH Rawalpindi 67. IV-Set 190803 CMH Rawalpindi 68. IV-Set 190804 CMH Rawalpindi 69. IV-Set 190805 CMH Rawalpindi 70. IV-Set 190806 ATD 71. IV-Set 190807 Murree 72. IV-Set 190808 CMH PSC 73. IV-Set 190809 CMH Nowshera 74. IV-Set 190810 CMH Nowshera 75. IV-Set 190811 CMH DI KHN 76. IV-Set 190813 CMH Lahore 77. IV-Set 190814 CMH Lahore 78. IV-Set 190815 CMH Lahore 79. IV-Set 190816 CMH MTI 80. IV-Set 190817 CMH Mir 81. IV-Set 190818 CMH Quetta 82. IV-Set 190819 CMH Sibbi 83. IV-Set 190828 PIMS Islamabad 84. IV-Set 190923 Govt.of Gilgit 85. IV-Set 190929 CMH Sialkot 86. IV-Set 190932 MCC KPK 87. IV-Set 190933 MCC KPK 88. IV-Set 190934 MCC KPK 89. IV-Set 190935 Bahawalpur Govt. 90. IV-Set 190936 MCC Buner 91. IV-Set 190937 MCC Charsada 92. IV-Set 190938 DHQ Bannu 93. IV-Set 190939 MTI Bannu 94. IV-Set 190940 MTI Bannu 95. IV-Set 190941 MTI Bannu 96. IV-Set 190942 MTI Peshawar 97. IV-Set 190943 MTI KPK 98. IV-Set 190944 MTI KPK 99. IV-Set 190945 MTI KPK 100. IV-Set 190946 MTI KPK 101. IV-Set 191001 MTI HMC Peshwar 102. IV-Set 191002 Pak Defence Force 103. IV-Set 191003 MCC DHQ DIR 104. IV-Set 191004 MCC KPK KTH 105. IV-Set 191006 MCC KPK KTH 106. IV-Set 191007 MTI KTH 107. IV-Set 191008 MTI KTH 108. IV-Set 191009 MS DHQ Peshawar 109. IV-Set 191010 MS DHQ Peshawar 110. IV-Set 191011 MCC Haripur 111. IV-Set 191012 DHQ Charsadda	
UNISA (Pvt) Limited	30	Disposable syringe 5ml with needle. (Blister pack)	Not Qualified	CE Certificate is not issued from EU NB under the relevant European directive for medical devices of European Union; Undertaking of "none of its manufactured batch sample has been declared Spurious/Adulterated since 2017 onward" since last two years	Not Prequalified	CE Certificate is not issued from EU NB under the relevant European directive for medical devices of European Union; Quoted product is not tried and tested in local environment for at least three years; Undertaking of "Any Spurious sample of quoted items" not attached		
UNISA (Pvt) Limited	28	Disposable Syringe 3ml with needle. (Blister pack)	Not Qualified	CE Certificate is not issued from EU NB under the relevant European directive for medical devices of European Union; Undertaking of "none of its manufactured batch sample has been declared Spurious/Adulterated since 2017 onward" since last two years	Not Prequalified	CE Certificate is not issued from EU NB under the relevant European directive for medical devices of European Union; Quoted product is not tried and tested in local environment for at least three years; Undertaking of "Any Spurious sample of quoted items" not attached		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Usmanco International	27	Disposable Syringe 20ml with needle. (Blister pack)	Not Qualified	Valid ISO 13485 of Principle JiangXi Sanxin Medtec Co., Ltd. not attached	Not Prequalified	Valid DRC/ Device Enlistment certificate not attached; Quoted product is not tried and tested in local environment for at least three years; Goods Declaration certificates of quoted items of last three years not attached	Sir, November 19, 2020 The Director General Health Services, Primary and Secondary Healthcare Department, Lahore Subject: GRIEVANCE AGAINST PRE-QUALIFICATION EVALUATION REPORT PREQUALIFICATION OF MANUFACTURING UNITS AND SOLE AGENTS OF FOREIGN PRINCIPALS FOR MEDICAL DEVICES 2020-2021 FOR DGHS, P&SHD. It has been intimated to us through your prequalification evaluation report that our items # 39,40,41,42,47,48,59,61 & 62 not prequalified in this prequalification with same remarks i.e. ''Quoted product is not tried and tested in local environment for at least three years; Goods Declaration certificates of quoted items of last three years not attached'' We have assumed that there is clerical error, during preparation of this evaluation report, we had submitted desired documents at the submission of prequalification through online portal and hard copies as well and again attached with this letter for your kind concern as enlisted below:- Item No. 39 I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 18G Quoted product is not tried and tested in local environment for at least three years Annex-A Goods Declaration certificates of quoted items of last three years Annex-B Item No. 40 I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 20G Quoted product is not tried and tested in local environment for at least three years Annex-C Goods Declaration certificates of quoted items of last three years Annex-D Item No. 41 I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 22G Quoted product is not tried and tested in local environment for at least three years Annex-E Goods Declaration certificates of quoted items of last three years Annex-F Item No. 42 I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 24G Quoted product is not tried and tested in local environment for at least three years Annex-G Goods Declaration certificates of quoted items of last three years Annex-H Item No. 47 Nasogastric tube (all sizes) Sterile Packs Quoted product is not tried and tested in local environment for at least three years Annex-I Goods Declaration certificates of quoted items of last three years Annex-J Item No. 48 Nelton Catheter Sterile Packs Quoted product is not tried and tested in local environment for at least three years Annex-K Goods Declaration certificates of quoted items of last three years Annex-L Item No. 59 Suction Catheter (All Sizes) Quoted product is not tried and tested in local environment for at least three years Annex-M Goods Declaration certificates of quoted items of last three years Annex-N Item No. 61 Three-way stopper with Tubing Quoted product is not tried and tested in local environment for at least three years Annex-O Goods Declaration certificates of quoted items of last three years Annex-P Item No. 62 Three-way stopper without Tubing Quoted product is not tried and tested in local environment for at least three years Annex-Q Goods Declaration certificates of quoted items of last three years Annex-R Furthermore, we also refer to our products participated against your items # 32 & 33 are also not pre-qualified in this prequalification with reason “DRC Not Provided” Please note Registration of Medical devices is currently on going under the new Medical Device rules 2018. It is currently being implemented in phases starting with Category D then C and onwards. Our mentioned items, which fall in Category B have so far not been awarded registrations for most companies and brands. We would like to inform you that Usmanco International has already applied for registration for this products and Fee Challan (deposit slip) with DRAP receiving’s are attached at the time of submissions of online and hard copies as well and again attached with this letter for your kind concern (Annex-S) Moreover, we have registered our case in Lahore High Court pertaining the delay in registration procedure and have successfully received stay order from LHC, which clearly stated that “Since interim relief has already been granted in connected matters, subject to notice for the said date, in the meanwhile, the respondents are restrained from requiring the applicant to be registered as the importer of medical devices with DRAP. They are also restrained from seizing by the DRAP and further restrained from demanding the NOC to be issued by the DRAP for the release of the goods imported by the petitioner subject to payment of other levies like sales tax and custom duties” (Annex-S) Further, a provisional list has been uploaded on DRAP website enlisting all those products that are under process for registration. There is currently a long pendency in registration process from their side. Copy of all these documents have been enclosed with this letter for your kind review (Annex-S) In view of the above facts we deserve a due consideration for necessary action at your end and promise you to submit valid DRAP registration for items # 32 & 33 at the earliest once received from DRAP. We hereby request you to review this matter and in the light of attached documents kindly prequalify us and our subjected products _____ Usmanco International	Mr. Syed Iftikhar Ahmed, RSM, from M/s Usmanco International attended the meeting and presented their grievance to the grievance redressal committee. The committee heard the view point of the representative of the firm which was examined in the light of Evaluation Report. The committee after due deliberation and discussion, keeping in view the evaluation criteria decided that: 1. The firm provided GDs & POs of I.V Cannula Size 18G, 20G, 22G & 24G; Nasogastric tube; Nelton Catheter; Suction Catheter of last three consecutively, which were **accepted**. 2. The firm did not provide GDs & POs of of last three consecutively Three way stopper: with Tubing & without Tubing. 3. The firm did not provide Valid DRC/ Device Enlistment certificate of Disposable syringe 1ml, 3ml, 5ml, 10ml, 20ml; Endotracheal tube (all sizes) Sterile Packs: with cuff Set & without cuff Set; Nelton Catheter; Three way stopper: with Tubing & without Tubing. Hence grievance of the firm was **accepted** and declared "**Prequalified**" for all quoted items **expect** disposable syringe 1ml, 3ml, 5ml, 10ml, 20ml; Endotracheal tube (all sizes) Sterile Packs: with cuff Set & without cuff Set; Nelton Catheter; Three way stopper: with Tubing & without Tubing.
Usmanco International	25	Disposable syringe 10ml with needle. (Blister pack)	Not Qualified	Valid ISO 13485 of Principle JiangXi Sanxin Medtec Co., Ltd. not attached	Not Prequalified	Valid DRC/ Device Enlistment certificate not attached; Quoted product is not tried and tested in local environment for at least three years; Goods Declaration certificates of quoted items of last three years not attached		
Usmanco International	26	Disposable Syringe 1ml with needle (Blister Pack)	Not Qualified	Valid ISO 13485 of Principle JiangXi Sanxin Medtec Co., Ltd. not attached	Not Prequalified	Valid DRC/ Device Enlistment certificate not attached; Quoted product is not tried and tested in local environment for at least three years; Goods Declaration certificates of quoted items of last three years not attached		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Usmanco International	28	Disposable Syringe 3ml with needle. (Blister pack)	Not Qualified	Valid ISO 13485 of Principle JiangXi Sanxin Medtec Co., Ltd. not attached	Not Prequalified	Valid DRC/ Device Enlistment certificate not attached; Quoted product is not tried and tested in local environment for at least three years; Goods Declaration certificates of quoted items of last three years not attached		
Usmanco International	30	Disposable syringe 5ml with needle. (Blister pack)	Not Qualified	Valid ISO 13485 of Principle JiangXi Sanxin Medtec Co., Ltd. not attached	Not Prequalified	Valid DRC/ Device Enlistment certificate not attached; Quoted product is not tried and tested in local environment for at least three years; Goods Declaration certificates of quoted items of last three years not attached		
Usmanco International	39	I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 18G	Qualified		Not Prequalified	Quoted product is not tried and tested in local environment for at least three years; Goods Declaration certificates of quoted items of last three years not attached		
Usmanco International	40	I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 20G	Qualified		Not Prequalified	Quoted product is not tried and tested in local environment for at least three years; Goods Declaration certificates of quoted items of last three years not attached		
Usmanco International	41	I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 22G	Qualified		Not Prequalified	Quoted product is not tried and tested in local environment for at least three years; Goods Declaration certificates of quoted items of last three years not attached		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Usmanco International	42	I.V Cannula with/without Injection Port with Integrated Closing Cone Sterile Pack 24G	Qualified		Not Prequalified	Quoted product is not tried and tested in local environment for at least three years; Goods Declaration certificates of quoted items of last three years not attached		
Usmanco International	59	Suction Catheter (All Sizes)	Qualified		Not Prequalified	Quoted product is not tried and tested in local environment for at least three years; Goods Declaration certificates of quoted items of last three years not attached		
Usmanco International	61	Three way stopper with Tubing	Qualified		Not Prequalified	Quoted product is not tried and tested in local environment for at least three years; Goods Declaration certificates of quoted items of last three years not attached		
Usmanco International	62	Three way stopper without Tubing	Qualified		Not Prequalified	Quoted product is not tried and tested in local environment for at least three years; Goods Declaration certificates of quoted items of last three years not attached		
Usmanco International	47	Nasogastric tube (all sizes) Sterile Packs	Qualified		Not Prequalified	Quoted product is not tried and tested in local environment for at least three years; Goods Declaration certificates of quoted items of last three years not attached		
Usmanco International	48	Nelton Catheter Sterile Packs	Qualified		Not Prequalified	Quoted product is not tried and tested in local environment for at least three years; Goods Declaration certificates of quoted items of last three years not attached		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
Usmanco International	33	Endotrac heal tube (all sizes) Sterile Packs without cuff Set	Not Qualified		Not Prequalified	DRC not provided		
Usmanco International	32	Endotrac heal tube (all sizes) Sterile Packs with cuff Set	Not Qualified		Not Prequalified	DRC not provided		
ZEDCO	12	Blood Bags Sterile Packs 250ml single	Not Qualified	Valid ISO 13485 not attached; Expired CE certificate of the Principle Terumo BCT, Ltd. United Kingdom; Minimum Annual financial turnover is less than Rs.300 Million; Valid registration of manufacturing firm with chamber of commerce from country of manufacture not attached	Not Prequalified	Valid DRC/ Device Enlistment certificate not attached; Expired CE certificate; Quoted product is not tried and tested in local environment for at least three years (2018); Copies of Goods Declaration certificates of quoted items of last three years not attached	Respected Sir, This is with reference to subject tender; we are hereby pleased to submit our clarification on technical evaluation againnst the "Technically Rejected" of our Bid For Item No. 12, 13, 14 (Annexure-A). so you are requested to be please considering this matter in the light of above clarification and consider our bid as Responsive. Thanking you for cooperation and assuring you of our best service at all, we remain.	Mr. Imran Usmani from M/s ZEDCO attended the meeting and presented their grievance to the grievance redressal committee. The committee heard the view point of the representative of the firm which was examined in the light of Evaluation Report. The committee after due deliberation and discussion, keeping in view the evaluation criteria decided that: 1. The firm provided valid ISO 13485 of Principal Terumo BCT, Ltd., which was **accepted**. 2. The firm provided valid CE certificate of the quoted items, which was **accepted**. 3. The firm provided FBR Sales Tax return as substantial evidence for annual financial turnover more than Rs.300 Million, which was **accepted**. 4. The firm provided registration of manufacturing firm with chamber of commerce, which was **accepted**. 5. The firm did not provide GDs & POs of last three years consecutively for Blood Bags and Blood Transfusion Set. Hence the grievance of the firm was **accepted** and status of all quoted items declared as "**Prequalified**".
ZEDCO	13	Blood Bags Sterile Packs 500ml single	Not Qualified	Valid ISO 13485 not attached; Expired CE certificate of the Principle Terumo BCT, Ltd. United Kingdom; Minimum Annual financial turnover is less than Rs.300 Million; Valid registration of manufacturing firm with chamber of commerce from country of manufacture not attached	Not Prequalified	Valid DRC/ Device Enlistment certificate not attached; Expired CE certificate; Quoted product is not tried and tested in local environment for at least three years (2018); Copies of Goods Declaration certificates of quoted items of last three years not attached		

Company Name	Inquiry No	Generic	Result	Firm Wise Reasons Of Rejection	Status	Item wise Reason of Rejection	Grievance of the Firm	Decision by the GRC
ZEDCO	14	Blood Transfusion Set Sterile Packs	Not Qualified	Valid ISO 13485 not attached; Expired CE certificate of the Principle Terumo BCT, Ltd. United Kingdom; Minimum Annual financial turnover is less than Rs.300 Million; Valid registration of manufacturing firm with chamber of commerce from country of manufacture not attached	Not Prequalified	Valid DRC/ Device Enlistment certificate not attached; Expired CE certificate; Quoted product is not tried and tested in local environment for at least three years (2018); Copies of Goods Declaration certificates of quoted items of last three years not attached		

Secretary Purchase Cell
(**Member**)

Senior Law Officer
(**Member**)

Program Manager, Hepatitis Prevention & Infection Control Program
(**Member**)

Program Director IRMNCH&NP
(**Member**)

Director Health Services (CD&EPC)
(**Convener**)