No. SO (PM&I) 2-1/2020-21/CPC(CRC)

GOVERNMENT OF SINDH
HEALTH DEPARTMENT

(PROCUREMENT MONITORING & INSPECTION)

Karachi, Dated, the 1st March, 2021

The Managing Director,
Sindh Public Procurement Regulatory Authority,
Karachi.

Sub: NIT REF: NO. 1813/2020 DATED: 19-07-2020 APPROVAL OF PROCUREMENT OF DRUGS / MEDICINES / SURGICAL SUNDRIES, DISPOSABLE ITEMS / SURGICAL SUTURE / DENTAL MATERIAL ITEMS UNDER CENTRALISED RATE CONTRACT 2020-21.

I am directed to enclose herewith copy of minutes of the meetings of Complaint Redressal Committee (CRC) for Tender No. 02 (Group: B & C), 03, 04 & 05 held on 12th February, 2021 under the Chairmanship of Secretary Health Sindh for further necessary action and hoisting on Authority's website, accordingly.

1.3.2021

(MUHAMMAD YAMEEN ABBASI)
SECTION OFFICER (PM&I)

C.C to:

1) The Chairman & All members of Central Procurement Committee (CPC), Health Department.
2) The Complainants (All) M/s. _____ along-with a copy of minutes of the meeting of CRC for information.
3) The P.S. to Minister Health Sindh.
4) The P.S to Secretary Health, Govt. of Sindh Karachi.

3/3/21

SECTION OFFICER (PM&I)

Please Host on Authority Website.

3/3/2021

ADC(R)

SPPRA INWARD DIARY
NO : 2560
DATED : 02/3/21

MINUTES OF THE MEETING OF COMPLAINT REDRESSAL COMMITTEE (CRC) FOR TENDER NO.02 (GROUP = B,C), 03, 04 & 05 HELD ON: 12TH FEBRUARY 2021

A meeting of Complaint Redressal Committee was held on 12th February 2021 under the Chairmanship of Secretary Health, Govt. of Sindh, in view of various complaints received from aggrieved bidder against technical/financial evaluation finalized by the Central Procurement Committee (CPC) [Technical Evaluation Committee (TEC) & Technical sub-committee] invited by Health Department under Centralized Rate Contract System for the year 2020-21. Following members of the committee attended the meeting:

1. **Dr. Kazim Hussain Jatoi**
   Secretary to Government of Sindh, Health Department.
2. **Professor Dr. Azra Saleem,**
   Professor of Pharmacology, SMBBMC Lyari, Karachi.
3. **Dr. Sikander Qureshi**
   Head and Dean Medicine & Allied, SMBBMC Lyari, Karachi.
4. **Dr. Ali Sheer Khaskheli**
   Asstt. Professor of Surgery, SMBBMC Lyari, Karachi.
5. **Mr. Naeem Liaquat,**
   Representative of Accountant General Sindh, Karachi.
6. **Dr. Abdul Jabbar Memon,** Additional Director Development Health has attended the meeting as Co-opt. Technical member.

All representatives of complainants attended the meeting. The representative of respective firms explained their complaints / grievances in detail before the Committee while the experts committee of CPC for evaluation produced relevant record for verification. The Committee examined and discussed the complaints thoroughly and after verification of relevant record and discussion, deliberation on each point and examination of all record, the Committee unanimously decided as under:

S.#	BIDDER NAME & GIST OF COMPLAINTS	DECISION OF CRC
1	**M/S. ALLMED SOLUTION** They have submitted grievances on following items: **Item No. SMD0169 (Camera cover Telescope folding, with cardboard insertion Aid).** **Item No. SMD0422 (ETT Tube coated with alloy of gold palladium & silver).** They stated that no point was included in evaluation report for both items and requested to re-evaluate. **Item No. SMD0461 (Foley Catheter coated with alloy of gold palladium & silver).** They are distributor of bactiguard AB but in above items they awarded less marks and also not awarded any marks in financial opening they quoted to re-evaluate.	The CRC examined the complaint and while reviewing of record produced by the CPC experts, observed that the complaint against item No. SMD 0169 & SMD0422 are baseless as both are available in BER. As far as item No. SMD0461, CRC referred the matter to CPC for review.

S.#	BIDDER NAME & GIST OF COMPLAINTS	DECISION OF CRC
2	**M/S. GENESIS INTERNATIONAL** They have submitted following reservations against items mentioned below:- Item No. XCM0036, XCM0037, XCM0038, XCM0039 = Contrast media: They stated that they have quoted above products and submitted all required documents but after reviewing comparative sheet, they have observed following: - During technical evaluation they were awarded 35 marks (they have signed that documents in front of the pharmacist), but in comparative they were given 28 marks in matrix – 1. - Against item # XCM0037 & XCM0038 the product demand by CPC committee in tender was Non-ionic Contrast media 350mgl/100 ml & 50 ml but the product awarded to Non-Ionic Contrast Media 370 mgl/100 ml & 50 ml. - In product evaluation matrix they given Zero marks in physical examination of quoted product even our product comes in glass container.	The CRC examined the complaint and as verification of record of CPC observed that cutting was found in marks of Matrix-I signed by the complainant. CRC shows displeasure and suggested that matter may be enquired properly. Moreover, marks for container is missing for complainant and approved product are not according to Tender specification, hence, CRC decided that Technical opinion may be obtained from Prof. of Radiology for further decisions.
3	**M/S. IMPERIAL TRADERS** They have submitted their grievances as under: 1. The Tender documents specified mandatory requirement / specification for Technical evaluation of manufacturer & importers. DRAP also promulgated the Medical Devices Rules-2017 for registration of Medical Devices but the Technical committee considered the non-enlisted firms and their products for evaluation without considering the MDR 2017 and awarded their items which otherwise be disqualified as per provision of clause g and h at page-144 of tender documents. 2. They also objected that evaluation committee evaluated non-registered firms and their products by either overlook the Technical evaluation criteria and prescribed proforma. 3. They objected that against evaluation following items their products declared non-responsive on the basis of marks on matrix-I. Due to not allocating 4 marks in Matri-I by not allocating 4 marks of GSP Inspection Medical Devices establishment license cannot issue GSP certificate separately. So, these 4 marks should be awarded in matrix-I, due to not allocating 4 marks they declared Non-responsive. Hence, their products was not evaluated physically. On the other hand their competitor have been awarded unjustified marks. Item Nos. SMD1151, SMD1152, SMD1153, SMD1154, SMD1155, SMD1156, SMD1157, SMD0236, SMD0292, SMD0350, SMD0351, SMD0352, SMD0353, SMD0444, SMD0445,	While hearing of complaint and views of CPC experts, observed that un-registered products were awarded. Moreover, GSP is not required for storage of Surgical / Disposable items. CRC unanimously decided that complainant may refer to CPC of review specially single quoted items of complainant as no alternate available for those items.

S.#	BIDDER NAME & GIST OF COMPLAINTS	DECISION OF CRC
	SMD0445, SMD0462, SMD0463, SMD0464, SMD0465, SMD0466, SMD0467, SMD0468, SMD0469, SMD0470, SMD0471, SMD0684, SMD0889, SMD0890, SMD0915, SMD0916, SMD0917, 0918, 1041, 1042, 1043, 1131, ANAESTHESIA DISPOSABLES. 4.SMD 0008, 0042, 0051, 0083, 0314, 0320, 0366, 0402, 0403, 0404, 0405, 0407, 0408, 0409, 0660, 0663, 0667, 1029, 1044, 1087, 1160 ECG DISPOSABLES. SMD0379, 0380 SURGEONS ATTIRE / WEARABLES. SMD0111, 0321, 1050, 1056, 1057, 1058. OTHERS. SMD0079, 0459, 0296, 0428, 0963. SCR0010, 0028. 4. They further stated that their following items were also declared non-responsive on the basis of nt obtaining the required marks on Matrix-I by not allocating 4 marks of qualified human resource, which should be awarded. SMD0524, 0835.	
4	**M/S RTJ ENTERPRIES.** Item Code: SMD0217 They have submitted their grievances as under: 1. The Tender documents specified mandatory requirement / specification for Technical evaluation of manufacturer & importers. DRAP also promulgated the Medical Devices Rules-2017 for registration of Medical Devices but the Technical committee considered the non-enlisted firms and their products for evaluation without considering the MDR 2017 and awarded their items which otherwise be disqualified as per provision of clause g and h at page-144 of tender documents. 2. They also objected that evaluation committee evaluated non-registered firms and their products by either overlook the Technical evaluation criteria and prescribed proforma. 3. Their product SMD0217 (Chloroxylenol solution 4.5 liters) declared responsive and secured 25 marks in matrix I and 30 marks in matrix II. As per evaluation criteria in both matrix participants secured 70% marks. But the product awarded to their competitor Pharmawise who secured 32 marks in matrix I and 23 marks in Matrix II which are less than required quantum i.e. 24.5 marks (70%) declared responsive which should be non responsive. On the above clarification they are requested for allow to necessary rectification.	The CRC after hearing of complainant and clarification submitted by CPC team observed that the approved product having 23 marks in Matrix-II, which require to review. As far as quality of product, expert opinion from surgeon may be obtained for further decision.

S.#	BIDDER NAME & GIST OF COMPLAINTS	DECISION OF CRC
5	**M/S KOHINOOR INDUSTRIES** The submitted that technical committee declared the "NR" due to expired mandatory documents, but they submitted valid mandatory documents in bid. They requested to re-check for given below dates and may stop till the decision of CRC . TENDER NO.02 GROUP-C SCR0007, 0008, 0009, 0017, 0034, 0035, 0054, 0055, 0056. TENDER NO.02 GROUP-B. SMD0834 & 0835.	The representative of complainant informed CRC that they have provided all valid documents including cGMP but CPC declared that NR on the basis of expired mandatory documents. CRC on review of complaint and BER record, decided that matter may be referred to CPC for review of documents.
6	**M/S MULLER & PHIPPS** They have submitted reservation on approval of items No.SMD0834 & smd0853 Povidone Solution 450 ml & Scrub in favour M/s Pharmawise and objected as under - Availability of 25% inventory: They are local manufacturer against quoted items same criteria donot fall as manufacturing unit. Kindly consider as manufacturer not "Importer". - Technical / bid documents submitted arranged documents & sequence, kindly grant three marks to Brooks Pharma.. - Non –Availability of export certificate M/s Pharmawise Labs. There is need to revaluate the export certificate of the firm name M/s Phamrwise Laboratories have not exporting Povidone Iodine Range in the local market recently (cancellation manufacturing license & stopped production). Your competent authority may verify the claim from Assistant Drug Controller of DRAP , Birdwood Road, Lahore that is a sole competent authority in Punjab to issue the NOC certificate for export. Kindly revaluate & deduct five marks M/s Pharmawise Lab. Export criteria. - Valid ISO 13485. M/s Pharmawise labs haven't valid ISO 13485, this ISO certificate fall foreign chain product as sole agent instead of local manufacturer. Your evaluation committee granted mistakenly four marks. Kindly deduct same four marks. - MCC KPK annual tender & rate contract 2020-21. Medicine Coordination Cell Kyber Pakhtunkhwa "Not Recommended" same firm for the financial 2020-21 due to unsatisfactory plant inspection recently, (report enclosed for your quick reference). Cancelation of Drug Manufacturing License M/s Pharmawise Labs. It is brought to your notice with great concern that the honourable Technical Committee of your esteemed hospital has "incorrectly approved the Technical Offer	The CRC examined the complaint and while reviewing of record observed that the issue of compatibility for items No. 0233, 0234, 0395, 0396 & 1093, 1101 are technical in nature, which should be reviewed through CPC. Moreover, approval of products against item no. 0219, 0220, 0221, 0233, 0234, 0395, 0396 may refer Prof. Amjad Siraj Memon & another Professor of Surgery for review & Technical opinion. Item No. 0131, 0134, 1035, 1036, 0132 may be referred to CPC for review.

S.#	BIDDER NAME & GIST OF COMPLAINTS	DECISION OF CRC
	of M/s Pharmawise Labs. Against item at Povidone Solution 450 ml & Scrub 450ml. As per Central Licensing Board meeting # 256 held on November 9-10, 2017 under the Chairmanship of Mr.Shaikh Faqeer Muhammad, Director Drug Licensing Drug Regulartory Authority of Pakistan. - They stated that following items were awarded to M/s. Wastan Medical China, there MDR is suspicious. SMD0219, 0220, 0221, 0233, 0234, 0395, 0396, - Following awarded products are not Ticolsan quoted polyglactin 910 (antibacterial) as demanded).1093, 1094, 1098, 1100, 1101, 0728 (all), - In following products WEGO quoted by two different vendors, creating a doubt of malpractice about the registration and authorization to other vendors SMD 0131, 0134, 1035, 1036, 0132	
7	**M/S POPULAR INTERNATIONAL** They have submitted reservations in two points (A-Sutures) & (B-Endo / Stippling Devises). **(A-Sutures):** Item No.SMD004, 0131, 0312, 0133, 0134, 0135, 0136, 0148, 0419, 0420, 0562, 0563, 0564, 0565, 0566, 0567, 0732, 0733, 0734, 0736, 0746, 0747, 0748, 0750, 0755, 0756, 0757, 0758, 0761, 0762, 0763, 0765, 0766, 0767, 0770, 0771, 0791, 0792, 0793, 0794, 0795, 0796, 0797, 0799, 0800, 0801, 0802, 0803, 0805, 0806, 0807, 0808, 0809, 0810, 0811, 0812, 0813, 0814, 0817, 0818, 0820, 0821, 0822, 0925, 0926, 0927, 0928, 0929, 0930, 0931, 0932, 0933, 0934, 0935, 1062, 1064, 1065, 1966, 0567, 0772, 0774, 0776, 0779, 0783 & 0887. - In above items, they got zero marks in above mentioned items against GD, Certificate of Analysis, Free Sale Certificate API source, valid CGMP / CE, FDA, ISO, valid free sale in its API and Physical Examination in our quoted products. While our manufacturer Covidine / Medtronic is located in USA and our all quoted suture product is US-FDA approved and CE marked , copy of CFG certificate issued by US-FDA, CE certificate and ISO certificate are again attached as "Annex-A". Also one single Free Sale Certificate , API source, valid CGMP / CE, FDA, ISO certificate cover all suture code so its beyond principle of natural justice how they have got marks in certain codes and not in other when there is single FDA, CE, ISO for all code. For example, they have got all marks in SMD0558 SMD0560, SMD0561 but not in other suture code.	The complainant explained about missing of numbers and then members of technical committee accepted the typing error which should be rectified by CPC, therefore referred to CPC and also to get expert opinion from Professor of Surgery (Prof. Amjad Siraj Memon).

S.#	BIDDER NAME & GIST OF COMPLAINTS	DECISION OF CRC
	- **M/s I R Enterprises** quoted for Atramat Suture, who does not have FORM 4 "product registration as Medical Device" and their suture are still registered in DRAP under Drug category, whereas as per SRO 824/2018 of DRAP, Suture is medial device and its should be registered under Medical Device Rule 2017 and only be sale as devices. - **M/s Akram Brother** Lahore has quoted WEGO China "Vicryl Suture" against below mentioned CPC codes and M/s Akram Brother has issued authority to M/s M.F Trader Hyderabad to quote same products and both has participated in the subject tender and quoted same products against each other, while as per as per tender specification under mandatory clause and SPPRA rules only sole agent or authorized distributor is allowed to quote each brand against each CPC code to participate in tender. Please disqualify WEGO China as they do not meet tender specifications. - **M/s A.M Distributor** has quoted Unimed, KSA suture, which as major recalls in last 3 years over the world due to "suture breaking strength are non-complaint to European Pharmacopeia requirements". Same as complain are arising in local market and local surgeon complain about Suture length and needle sharpness. **Grievance against.** **CPC CODE # SMD0562, 0563, 0564, 0565, 0566 & 0567.** In the Serial, health department has demanded lactomer 9-1 which is property salt of Medtronic / Covidien, but AM distributor and B.Braun has tried to misguide the committee by quoting POLYGLOIC acid which is already demanded as other serial numbers and has not been awarded to them if is same thing there is no use of separate CPC CODE / SMD numbers. Only Polysorb suture are composed of Lactomer glycolide / lactide copolymer, which is a synthetic polyester composed of glycolide and lactide (derived from glycolic and lactic acids). They are prepared by coating the suture with a mixture of a caprolactone / glycolide copolymer and calcium strearoly lactylate. Price list of AM Distributor attached, as evidence. **Grievance against.**	

S.#	BIDDER NAME & GIST OF COMPLAINTS	DECISION OF CRC
	CPC CODE # SMD091, 0792, 0793, 0794, 0795, 0796 & 0977. In these serial health department has demanded monofilament polyglyconate which is property material of Covidien Mxon Suture. M/s AM Distributor has tried to misguide the committee by quoting POLYDIXONE ie Unicryl M, which is ready demanded as other serial numbers and has not been awarded to them. If is same thing there is no use of separate CPC CODE / SMD numbers. ONLY MAXON synthetic absorbable sutures are prepared from POLYGLYCONATE, a copolymer of glycolic acid and trimethylence carbonate. Price list of AM Distributor attached as evidence. **(B-ENDO / STUPPING ITEMS)** Grievance -1. They got zero marks in below mentioned items against GD, Certificate of Analysis, Free Sale Certificate, CE Certificate, API source, valid CGMP/CE, FDA, ISO and Physical Examinattion in our quoted products. While our manufacturer Covidien / Medicine is located in USA and our all-quoted Suture product is US FDA approved and CE marked, copy of CFG certificate issued by US-FDA, CE certificate and ISO certificate are again attached as "Annexure A". Also one single Free Sale Certificate, API source, valid CGMP / CE, FDA, ISO certificate cover all stapling codes, so it's beyond principle of natural justice how we have got marks in certain codes and not in below when there is single FDA, CE, ISO for all codes. For example, we have got all marks SMD-0598, SMD-6002, where we have got full marks so we are amazed and surprised by this in justice. Further M/S Rech International has quoted stapling devices manufactured by Chagzhou Watson Medical Appliance Co, China. They have not provided documents like FDA, ISO 1400 14001 and also do not have any clinical trial wordwide and in the local market. Whereas Medtronic, USA has world wide surgery for years and have confidence in the product. Products like Circular Stapler and Endo Stapler are used in advance cancer surgery and failure of products may lead to death of the patients. **SMD-0233, SMD0394, SMD0395.** The item quoted by M/s Rech International are not registered with DRAP ARE and they have mentioned fake registration numbers, we would request the honourable committee to take strict action to prevent companies from playing with patient life and laws of Pakistan.	

S.#	BIDDER NAME & GIST OF COMPLAINTS	DECISION OF CRC
	SMD0996, SMD-0997, SMD0998, SMD1000, SMD1001 Secondly the technology they are claiming / offering is the invention and patent of M/s Medtronic , USA (Tri-Stapler Technology). Also the reload quoted by M/s Rech International are not compatible with Signia stapling system which is purchase by hospital for million and will make huge investment of govt of Sindh worth less. SMD0908, SMD-0996, SMD0999, SMD0234, SMD0997, SMD1000, SMD0998, SMD1001, SMD1123 & SMD1122. **Grievance – 2** We got zero marks in below mentioned items against Physical Examination in our quoted products. While we submitted all items samples to your good office, letter of sample submission is again attached as "Annexure B". All below products are in used form last many years in all CPC instiutues without any complaint, if this item are not considered than hospital authorities may have to purchase thee on high rates on LP, Also the item are disposable / consumable of equipment which may become useless. SMD0125, SMD0233, SMD0358, SMD0017, SMD0024, SMD0883, SMD0015, SMD0016, SMD0022, SMD0039, SMD0623, SMD0837 & SMD0532. **Grievance # 3** In below mentioned item are non-compatible with equipment available in Sing Govt. hospital. The item is especially demanding REM paid for FT paid for FT and not normal diathermy pads which are already covered in other serial numbers. Value of each equipment is approx. 5 million each, which may be malfunctioned due to non-compatible consumables, may cause burned injury to the patients. SMD0044 & SMD0296.	
8	**M/S SITECH PHARMACEUTICAL** They have submitted that reservation for item No.SCM0037 & 0036 Contrast Media and stated that the approval product does not meet the specification given in tender documents . They stated that according to tender "Non – Ionic Contrast Injection CT Scanner 350 100ml & 50 ml required but approval products not as per tender specification 370 100ml & 50ml.	While reviewing of complaint & verification of CPC record, CRC observed that the complaint is same as discussed at Sr. No. 02 of M/s. Genesis International hence same decision for obtaining of comments from Professor of Radiology for review.

S.#	BIDDER NAME & GIST OF COMPLAINTS	DECISION OF CRC
9	**M/S SKY PHARMA** They submitted their reservations as under: - In following items i.e., SMD0007, 0009, 0305, 0487, 0487, 0489 & 0606, their products declared non responsive on the basis of not obtaining the required 29 marks by not allocating of analysis, which may please be allowed and necessary rectification kindly made in BER. They further submitted that on physical verification of samples difference marks were given to the same products of different volume which are to be rectified. - In items nos. SMD0048 & 1091 the technical evaluations had been carried out as per provided criteria and following discrepancies noted that our competitor ahs been made responsive at 27 marks in products matrix 2 which are less than 70% as mandatory requirement. However they obtained the 29 marks in both matrix which is above than 70% but their product was declared was non responsive which may please be rectified and same may be awarded in favor. - In items nos, SMD0266, 1045, 1046, 1047, & 1048, their product declared non responsive on the basis of not obtaining the required 29 marks by not allocating 5 marks of certificate of analysis. Which may please be allowed and necessary rectification kindly made in BER. - In items nos. SMD1241, 1242, 1243, 1244 & 0635. As per BER they obtained requird maks and each matrix that is 29 marks (70%), but the technical committee declared us is nonresponsive. However our competitors. M/s Medinostic health care pvt. Ltd. Secured 28 ,arks in matrix 2 which are less than required quantum i.e 29 marks (70%) declared responsive. Which shall non responsive otherwise. M/s Staincos Pvt. Ltd. Is a manufacturer of cosmetics and non enlisted firms by the DRAP in according MDR 1017 SMD1243. As per provision of section V clause 4 (g) of tender documents, non registered firms were not eligible to participate in tender. It is therefore requested the firms may please be declared non responsive . Disqualified and the marks allocated on the basis of the requirements that the GSP, HVAC, cGMP & export certificate from DRAP may also be considered null and vide. One the above clarification it is requested that necessary certification may please be allowed in our favor. - In items nos. SMD0541 & 0630, their product declared non responsive on the basis of not obtaining the required 20 marks by not allocating marks for 25% of stocks = 5 marks and ISO 13485 = 3 marks in matrix 1	While hearing of complaint and review of record, CRC observed that there are difference in marks of same items of different size, which should be reviewed. Moreover, complainant got qualifying marks in Matrix-II for Item No. 0048 & 1091 but due to oversight financial rates were not incorporated in comparative statement. It is also observed that approved brand of Hand sanitizer of M/s. Stancos, which is a cosmetic company. For item No. 1241 & 1242, CRC required to get comments that these items are in use of O.T. or not. In view of above, CRC unanimously decided that the observation of complainant may be verified from original record through CPC.

S.#	BIDDER NAME & GIST OF COMPLAINTS	DECISION OF CRC
	and certificate of analysis 5 marks in matrix 2, the same documents in original verified by the technical evolution committee at the time of documents.Due to not allocating 8 marks in matrix 1 we had declared non responsive hence our products was not evaluated physically. It is further stated that during 2019-20, while our product secure 15 marks on physical.	
10	**M/S SKY WAYS INTERNATIONAL** 1. They stated that they have quoted following products of the Importer (M/s Asian Fibre) but their marks were not calculated properly as the same company declared "Responsive" quoted by M/s Saad Sales Services but "Non-Responsive" declared quoted by the complaint. Item No. SMD0897, 0898, 0899, 0952, 0953, 0661, 0662 & 0963. 2. In item No.SMD131, their quoted product with the importer M/s SY' AH Impex), was also not calculated properly. 3. They further stated in tender 02 (group-C) they have offered following item. SCR002, 003, 004, 0057, 0058, 0059, 0060 & 0067. But in comparative statement they were declared "responsive" in item No. SCR002, but in their item they were not shown. If they are responsive in SCR002 why their name not appear in other items. 4. They also objected that in Tender-02(Group-B) following marks were not awarded to them or awarded less marks: - Availability of minimum 25% inventory=no marks. - Valid ISO 14001 certificate=no marks - Valid ISO 9001 certificate= no marks. - API/RAW=5 marks	CRC examined the complaint and after verification of record unanimously decided that Cotton related products quoted by them are not shown in online BER, which may be verified from I/T personals of CPC (Mr. Abdul Mannan of DUHS). Moreover, for item No. SMD0131, CRC feels that calculation of product was not properly made, which may be reviewed by CPC.
11	**M/S SHAMIM & CO.** Tender No-02 (B) They have submitted / forwarded complaint against Item No.SMD0304, 1243 & 1244, received from the Principal company as per detail given below. SMD0304. Disinfectant tissues based on propan. 1. They M/s Medinostic health care have submitted the GSP letter with our bid. They are also a DRAP approved importer and our GSP are evaluated by DRAP & approval was given after this evaluation. (Copy of letter attached) 2. The product that was approved for, have not following documents / certification which is compulsory of utmost bidding requirement to evaluate product quality. • DRAP Registration / Enlistment (As per DRAP rules, a product not yet registered can't be marked or sold. • The company have awarded 2 additional points for	While reviewing of complaint & CPC record verified, CRC observed that for product SMD0304 under registration to DRAP to be checked by CPC. As far as item no. XCM0040, the complainant is single quoted, hence CPC may review, if necessary.

S.#	BIDDER NAME & GIST OF COMPLAINTS	DECISION OF CRC
	USFDA however FDA doesn't regulate disinfectant wipes for surface disinfection (https://www.fda.gov/cosmetices/cosmetic-product/disposable-wipes) so there can be no FDA approval for disinfectant wipes for any brand. Kindly remove the additional 2 points. • No brand name & manufacture wipes for any brand. Kindly remove the additional 2 points. • ISO quality certification (ISO 9001 ; 14001). • M/s Benchmark might have submitted ISO 13485 certificate which have awarded 3 points however, company didn't submitted ISO 9001 certificate which is pre-requisite of ISO:13485 certifications. **SMD1243** Hand Sanitizer with 70% or above IPA (Isopropyl Alcohol)/80% or above Ethanol. **SMD1244** Hand Sanitizer with 70% or above IPA (Isopropyl Alcohol)/80% or above Ethanol. 1.M/s Medinostic health care have submitted the GSP letter with our bid. They are also a DRAP approved importer and or GSP are evaluated by DRAP & approval was given after this evaluation. (Copy of letter attached). • The approve brand of PRO-SAN has not been registered with DRAP. • The company have granted 5 points for export certificate issued by DRAP, However, the Manufacturer is not DRAP approved, therefore can't be issued a DRAP export certificate. Kindly remove these additional 5 marks. • In addition to above, the approved product doesn't have any product relaed quality certificate (i.e ISO 13485; CE etc). nor have CoA of Finished Goods and also not have 25% inventory as per the tender requirement. They only have basic ISO9001 management certification, which does not represent product quality. **Tender No-02 (C).** They submitted griaencies against item No.SCR0027 & SCR0043 that their principal company M/s Uniferoze informed that they have awarded less marks in evaluation. They stated that they have submitted all relevant but marks were not given in following.	

Evaluation criteria for cotton related items / Bandage etc 2020-21.	Marks Awarded
Availability of minimum 25% inventory of the total importer of the quoted items.	0
Valid cGMP by DRAP	0
Valid cGMP/CE + ISO 13485	0
Good Declaration certificate of imported API	N/A

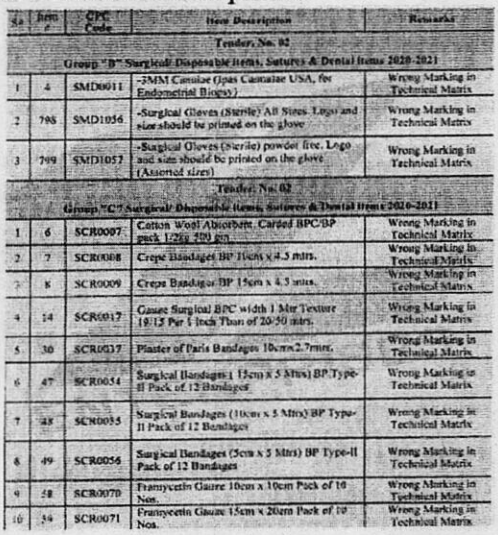
<table>
<tr><th>S.#</th><th>BIDDER NAME &
GIST OF COMPLAINTS</th><th>DECISION OF CRC</th></tr>
<tr><td></td><td>Tender No-03.
They stated that they have quoted item No. NCM0040 of Sky Gel, ISD Meditech SDN BDH Malysia but in Physical examination CPC experts given 05 marks instead of 15 which they deserve.</td><td></td></tr>
<tr><td>12</td><td><u>M/S SINDH MEDICAL STORES</u>
They have stated that their following products were not considered in financial process despite their prices are lowest and requested to consider.
<table>
<tr><th>CPC CODE</th><th>TENDER NAME</th><th>QUOTED PRICE</th></tr>
<tr><td>SMD 0801</td><td>Polypropylene 0, 40 mm 12 circle Round body 75 cm</td><td>153.33</td></tr>
<tr><td>SMD 0803</td><td>Polypropylene 1, 40 mm 12 circle Round body 75 cm</td><td>173.33</td></tr>
<tr><td>SMD 0814</td><td>Polypropylene 4/0, 20 mm 12 circle Round body 75 cm</td><td>170.00</td></tr>
</table></td><td>While reviewing of complainant reservations and review of record CRC decided that the complaint is baseless, hence rejected.</td></tr>
<tr><td>13</td><td><u>M/S SADQAIN HEALTH CARE</u>
Tender No.2 (Group-B)
SMD0042m 0051, 0054, 0088, 0228, 0314, 0317, 0322, 0323, 0324, 0325, 0326, 0327, 0652, 0660, 0667, 0668, 0854 & 1160
They submitted their observation against above items as under.
1. Awarded product is not register in DRAP.
2. Whereas our all certificates and products registration certificate from DRAP are submitted and verified by CPC experts.
3. GSP Certificate – 4 marks desere, but Zero mark were given to M/s Sadquain Health Care.</td><td>While reviewing of complainant reservations and review of record CRC decided that the complaint is baseless, hence rejected.</td></tr>
<tr><td>14</td><td><u>M/S. SEARLE COMPANY</u>
They submitted that their quoted products against items No.SMD 1056 & 1057 were declared “Non – Responsive” due to not security 70% marks in Matrix –II. They submitted grievance as under:
1. Technical centre give 05 marks in physical examination, which should be considered given facts.
The Searle company is a most reputed 2nd largest medical company of Pakistan & for disposables our manufacture TOP GLOVE is the world’s largest manufacturer of quality gloves producing 93-billion gloves per annum, having 47 factories and exporting to 193 countries including developed countries like USA, UK, Germany, France, Italy, Canada & Australia etc.
They supplying these surgical gloves to public & private institutions of Pakistan Trauma Centre Civil Karachi, DUHS, JPMC, Aga Khan, LNH, Indus Hospital, LBRT,</td><td>CRC examined the complaint & reviewing of physical marketing marking, it is observed that the product quoted by M/s. Searle is quality product and equal to approved brand but there is difference in physical marking awarded by Professors. CRC refer the matter to CPC for review by assistance of expert committee.</td></tr>
</table>

S.#	BIDDER NAME & GIST OF COMPLAINTS	DECISION OF CRC
	Tabba Heart, Tabba Kidney, Zia ud din Hospital, Services Hospital , Pins Lahore LRH Peshawar, North West Hospital Etc. (Pos attached for your reference) are a few of our satisfied customers. Leading consultants have their positive views on quality of our PROTIEX Latex Surgical Gloves. I also attached approvals on ground of quality from Jinnah & Civil Hospital Karachi. 2. 05 marks have been awarded in Raw Material Source, which should beconsidred07 on complying the source is US-FDA imported facility . 3. They have provided ISO 9001 certificate legalized from Embassy of Pakistan Original dots were verified by CPC exports at the time of authenticity check at Ojha Campus marks were not given.	
15	**M/S VIKOR ENTERPRIES.** They have submitted grievances on following range of items: 1. Catgut chromic sutures (item code from SMD0175 to 0195. 2. Silk suture (item code from SMD0923 to SMD0931). The detail grievances are as under: a) They are not been marked for certificate of Analysis of finish . Catgut Chromic Suture (item Code from SMD0175 till SMD0195) **In Factory Score:** Foosin WEGO (Akram Brothers) has been marked for ISO 9001, Iso 14001 and ISO 13485 (bid evaluation report copy attached here as Annexure-A), whereas the scope of certificate of Foosin WEGO doesn't cover Catgut Chromic Suture, as all certification bodies categorically mention the scope of activities the company is certified for and all certificates are available on certifying body's (TUV) website at www.tuvsud.com/en/services/product-certification/pc-cert (attached are the copies of screen shots of certificate on TUV website as annexure C, where all products which are covered in the scope of certification are categorically mentioned), and they do understand it is difficult for anybody to review each page, line and word of each document and is an unintentional error. Foosin WEGO are also being awarded with full marks for valid accreditation of manufacturing unit or its relevant section /s by International Body (Certificate from US-FDA, WHO and / or other accrediting body from SRA country / ies duly attested by senior, for Catgut Chromic Sutures (bid evaluation report copy attached here as Annexure-A). Whereas their suture manufacturing Factory is not have any accreditation but WEGO has 9 different industrial	CRC having the grievances of complainant and while reviewing of record produced by the CPC experts, observed that the matter has already in discussion in the complainant at Sr. No. 06 & 07. Moreover, in item no. SMD0175 to 0195, marks of certificate of analysis were not given to them as they are manufacturing sutures locally. CRC unanimously decided that complaint may be referred to CPC for review.

S.#	BIDDER NAME & GIST OF COMPLAINTS	DECISION OF CRC
	groups and more than 30 subsidiaries, so need to confirm from the scope of that accreditation certificate needs to be reviewed as their suture manufacturing plan does not have any accreditation Also can be confirmed from their website and by reviewing the certificate they has submitted also to be mentioned in suture their few products have FDA 510 approvals but not factory and also not Catgut Chromic suture. In product Score : Foosin WEGO China (Akram Brothers) has been marked for API/s /RAW source accredited by WHO, US-FDA, EMA, MHRA, TGA, PMDA, Swiss Medic or Health Canada or by other SRAs=07 and other source=05 (Relevant documents duly attested by senior executive of the importer) Maximum 7 marks, for Catgut Chromic (bid evaluation report copy attached here as Annexure-A), Whereas they are not again the certificate if they had submitted needs to reviewed for the scope mentioned in the certificate. Foosin WEGO China (Akram Brothers) has been marked for Valid ISO 10993 certificate issued by authorized body of the country of origin duly accredited with International Accreditation Forum (IAF), (duly attested by senior executive of the firm) for Catgut Suture (bid evaluation repot copy attached here as Annexure-A) but in reality they does not have and has been checked and confirmed , they never mention on their product or website also, and if any document is submitted that needs to checked and confirmed. Foosin WEGO China (Akram Brothers) has been marked for physical examination of quoted item whereas their Catgut Suture is needed to be classified as misbranded as per DRAP ACT, because on their display carton and individual Sachet, the method of sterilization they mentioned in English says R means sterilized GAMMA Radiation but in Urdu it says Sterilized EO Ethylene Oxide Gas (Attached are the snaps of WEGO Catgut Sutures carton and Sachet for your review and perusal as annexure D). Also the same brand (WEGO are being made non responsive on the basis of same by MCC KPK (can be checked and confirm from MCC KPK website their initial evaluation report and Final Evaluation list) and many other Government Institutes (proves can be provided if required). Not only WEGO there are many other companies if they see the scope of certificate specifically for Catgut Chromic Sutures are not covered for ISO certification, CE mark and also FDA approvals, as first their API (Catgut Thread) are not as per required standard many of them are not even registered in local regulatory	

S.#	BIDDER NAME & GIST OF COMPLAINTS	DECISION OF CRC
	authorities also are in China, their quality of product and packaging is not as per required standard so cannot be certificated by any certifying body (attached photo in Annexure D also can bee the quality they put the product in an ordinary plastic sachet) which itself is a big question mark on the stability of the product specially with fluid and sterilized must be packed in non inhalable packing whereas they are not so no one can certify the these products. SILK SUTURES (ITEM CODE FROM SMD0923 TILL SMD0931) In Factory Score : Huaiyin Medical Instruments China (KS Agencies) has been marked for ISO 9001, ISO 14001 and ISO 13485 (bid evaluation report copy attached here as Annexure A), Whereas the scope of as on website on Alibaba it does not cover suture. Foosin WEGO China (Akram Brothers) and Huaiyin Medical Instruments China (KS Agencies) are also being awarded with full marks for valid accreditation of manufacturing unit or its relevant section/s by International Body (Certificate from US-FDA, WHO and /or other accrediting body from SRA country/ies duly attested by senior , for silk suture (bid evaluation report copy attached) here as Annexure-A). Whereas mentioned above their Suture manufacturing Factory does not have any accreditation , so if they had submitted any such document need to be confirmed for the scope of that accreditation certificate, also can be confirmed from their website. In Product Score: Foosin WEGO China (Akram Bothers) and Huaiyin Medical Instruments China (KS Agencies) had been market for API/RAW source accredited by WHO, US-FDA, EMA, MHRA, TGA, PMDA, Swiss Medic or Health Canada or by other SRAs=07 and other source=05 (Relevant documents duly attested by senior executive of the importer) Maximum 7 marks, for silk (bid evolution report copy attached here as Annexure A) but they does not have any such accreditation as per our information but again the certificate if they had submitted needs to reviewed for he scope mentioned in the cerficates Foosin WEGO China (Akram Brothers) and Huaiyin Medical Instruments China (KS Agencies) has been market for valid ISO 10993 certificate issued by authorized body of they country of origin duly accredited with International Accreditation Forum (IAF), (duly attested by senior executive of the firm) for Silk Sutures (bid evaluation report copy attached here as	

<table>
<tr><th>S.#</th><th>BIDDER NAME &
GIST OF COMPLAINTS</th><th>DECISION OF CRC</th></tr>
<tr><td></td><td>Annexure A). But again as per our knowledge and confirmation they are not, so need to be checked and confirmed, they never mention on their product or website also.
b) Also in product score, they are not being marked
c) On the other hand few firms products (only in the quoted item) by mistake are being scored in correctly.
d) In silk suture.</td><td></td></tr>
<tr><td>16</td><td><u>M/S Z.I. ENTERPRISES</u>
They have submitted their grievances against following items, in the basis of wrong marking in Matrix.
Tender No.2 (B)
SMD0013, 1056 & 1057.
Tender No.2 (C)
SCR0007, 0008, 0009, 0017, 0037, 0054, 0055, 0056, 0070, 0071
Item wise detail grievances are attached in enclosed Annexure with the complaint.
<table>
<tr><th>Sr</th><th>Item #</th><th>CPC Code</th><th>Item Description</th><th>Remarks</th></tr>
<tr><td colspan="5">Tender. No. 02
Group "B" Surgical/ Disposable items, Sutures & Dental items 2020-2021</td></tr>
<tr><td>1</td><td>4</td><td>SMD0011</td><td>-3MM Camulae (Ipas Camulae USA, for Endometrial Biopsy)</td><td>Wrong Marking in Technical Matrix</td></tr>
<tr><td>2</td><td>798</td><td>SMD1056</td><td>-Surgical Gloves (Sterile) All Sizes. Logo and size should be printed on the glove</td><td>Wrong Marking in Technical Matrix</td></tr>
<tr><td>3</td><td>799</td><td>SMD1057</td><td>-Surgical Gloves (Sterile) powder free. Logo and size should be printed on the glove (Assorted sizes)</td><td>Wrong Marking in Technical Matrix</td></tr>
<tr><td colspan="5">Tender. No. 02
Group "C" Surgical/ Disposable items, Sutures & Dental items 2020-2021</td></tr>
<tr><td>1</td><td>6</td><td>SCR0007</td><td>Cotton Wool Absorbent. Carded BPC/BP pack 1/2kg 500 gm.</td><td>Wrong Marking in Technical Matrix</td></tr>
<tr><td>2</td><td>7</td><td>SCR0008</td><td>Crepe Bandages BP 10cm x 4.5 mtrs.</td><td>Wrong Marking in Technical Matrix</td></tr>
<tr><td>3</td><td>8</td><td>SCR0009</td><td>Crepe Bandages BP 15cm x 4.5 mtrs.</td><td>Wrong Marking in Technical Matrix</td></tr>
<tr><td>4</td><td>14</td><td>SCR0017</td><td>Gauze Surgical BPC width 1 Mtr Texture 19/15 Per 1 Inch Than of 20/50 mtrs.</td><td>Wrong Marking in Technical Matrix</td></tr>
<tr><td>5</td><td>30</td><td>SCR0037</td><td>Plaster of Paris Bandages 10cmx2.7mtrs.</td><td>Wrong Marking in Technical Matrix</td></tr>
<tr><td>6</td><td>47</td><td>SCR0054</td><td>Surgical Bandages (15cm x 5 Mtrs) BP Type-II Pack of 12 Bandages</td><td>Wrong Marking in Technical Matrix</td></tr>
<tr><td>7</td><td>48</td><td>SCR0055</td><td>Surgical Bandages (10cm x 5 Mtrs) BP Type-II Pack of 12 Bandages</td><td>Wrong Marking in Technical Matrix</td></tr>
<tr><td>8</td><td>49</td><td>SCR0056</td><td>Surgical Bandages (5cm x 5 Mtrs) BP Type-II Pack of 12 Bandages</td><td>Wrong Marking in Technical Matrix</td></tr>
<tr><td>9</td><td>58</td><td>SCR0070</td><td>Framycetin Gauze 10cm x 10cm Pack of 10 Nos.</td><td>Wrong Marking in Technical Matrix</td></tr>
<tr><td>10</td><td>59</td><td>SCR0071</td><td>Framycetin Gauze 15cm x 20cm Pack of 10 Nos.</td><td>Wrong Marking in Technical Matrix</td></tr>
</table>
They observed that the marking is based on undue favouritism and victimization of their quoted items and companies due to undue manner for which they seek support from the honourable Complaint Redressal Committee.</td><td>While reviewing of complaint & verification of record, CRC decided that complaint baseless, hence rejected.</td></tr>
<tr><td>17</td><td><u>M/S ZEDCO</u>
Item No.SMD0141, 0142 & 0143.
They have submitted their grievances against above items as under:
1. Approved product is technically rejected by many Government institutes.
2. As per DRAP rules all Blood Bags incorporating anticoagulants are in Class D but approved product in registered in Class C.
3. CE certificate is not from country of origin.</td><td>In view of the reservations of complainant and intimation that Dow University of Health Sciences & JPMC rejected approved company WEGO due to its quality but the same was approved in this Tender. CRC refered the matter to CPC for review.</td></tr>
</table>



S.#	BIDDER NAME & GIST OF COMPLAINTS	DECISION OF CRC
18	**M/S M.I. ENTERPRISES** Tender No.2 (B), SMD0175, 0176, 0177, 0178, 179, 0180, 0181, 0182, 0183, 0184, 0185, 0186, 0187, 0188, 0189, 0190, 0191, 0192, 0193, 0194, 0195, 0729, 0730, 0731, 0732, 0733, 0734, 0736, 0737, 0755, 0757, 0758, 0759, 0760, 0761, 0762, 0763, 0764, 0765, 0766, 0767, 0768, 0769. 0799, 0800, 0801, 0802, 0803, 0804, 0804, 0805, 0806, 0807, 0808, 0809, 0810, 0811, 0812, 0813, 0814, 0815, 0816, 0817, 0818, 0819, 0820, 0821, 0822 They objected that as per BER allocated marks for M/s. M.I. Enterprises (K.S. Agencies Importer) as in samples i.e. 08 marks. They are supplying Surgical Sutures for last three years through MSD tender in allover Sindh and not found given any complaint from any institute they given 08 marks of except 02 sizes and been disqualified from Matrix-II. M/s. Akram Brothers Importer of Sutures manufactured by Foosin Medical supplies have been given 4 extra marks of FDA sources in Chromic Catgut. But these sutures are not approved by FDA as mentioned in Wego website as well as FDA website. They requested for necessary correction may allowed for the justice and transparency. As per BER allocated marks for API for M/s. M.I. Enterprises (K.S. Agencies Importer) for Poly Glychoic Acid i.e. 5 but it is to stated that their PGA raw material are FDA approved so kindly be allocated 7 marks instead of % marks. For item Code: 0131, 0132, 0133, 0134, 0135, 0925, 0926, 0927, 0928, 0929 & 0930. As per BER allocated marks for M/s. M.I. Enterprises (K.S. Agencies Importer) as: Importer=26 marks Responsive Product=25 marks non responsive. While on scrutiny, they was observed that the samples marks allocated are 8 while in our other size of silk have been allocated 12 marks and responsive. After redressing the grievance and verifying samples marks. Importer = 26 marks Responsive Product=29 marks Responsive.	After heard of description by the complainant and perused of record, the CRC rejected the complaint.
19	**M/S LAB LINK ENTERPRISES** Tender No.2 (B), Item no. SMD0158, 0684 **For item code: SMD0158 Butterfly Needle:** **Technical Evaluation criteria** a. Valid accreditation of manufacturing unit or its relevant section by International Body (Certificate from USA-FDA, WHO and/or other accrediting body from SRA country/ies duly attested by senior executive of the firm). They objected that the firm technically approved by the	CRC listen the complaint that 04 marks of us accreditation was awarded to winning bidder in item No. 0158 but last year same firm got 0 marks. Moreover, 07 marks of API/Raw sources were awarded to them but certificate was not available with them. CRC referred the observations to CPC for review and check.

S.#	BIDDER NAME & GIST OF COMPLAINTS	DECISION OF CRC
	CPC Committee awarded the 4 marks in above mentioned Clause of technical evaluation criteria but as per the record available of previous evaluation they don't have valid accreditation and awarded 0 marks in the same clause also they don't have the US-FDA WHO nor they have any valid accreditation from SRA Countries. b.API/s Raw souce accreditaed WHO,US-FDA, EMA, MHRA, TGA, PDMA, Swiss Medic or Health Canada or by other SRAa countries. They informed that the firm technically approved by theh CPC Committee awarded the 7 marks in above mentioned Clause of technical evaluation criteria but as per the previous evaluation record they don't have valid accreditation from WFO, FDA or by SRAs Countries and awarded 3 marks in the same clause also they don't have the US-FDA, WHO nor they have any valid accreditation from SRA countries. **For item code: SMD0684 IV Chamber:** **Technical Evaluation criteria** c. Valid accreditation of manufacturing unit or its relevant section by International Body (Certificate from USA-FDA, WHO and/or other accrediting body from SRA country/ies duly attested by senior executive of the firm).They informed that the firm technically approved by the CPC Committee awarded the 4 marks in above mentioned Clause of technical evaluation criteria but as per the record available of previous evaluation they don't have valid accreditation and awarded 0 marks in the same clause also they don't have the US-FDA WHO nor they have any valid accreditation from SRA Countries. d. API/s Raw souce accreditaed WHO,US-FDA, EMA, MHRA, TGA, PDMA, Swiss Medic or Health Canada or by other SRAa countries. They informed that the firm technically approved by theh CPC Committee awarded the 7 marks in above mentioned Clause of technical evaluation criteria but as per the previous evaluation record they don't have valid accreditation from WFO, FDA or by SRAs Countries and awarded 3 marks in the same clause also they don't have the US-FDA, WHO nor they have any valid accreditation from SRA countries. c. Physical examination of the quoted item/s by the CPC expert/s. Rejection of the quoted item/s by the CPC expert/s shall lead to disqualification of the said item/s. They objected that the firm technically approved by the CPC committee awarded the 14 full marks in above mentioned clause of technical evaluation criteria but the quality of their product is very poor as compare to product of M/s. Lab Link.	

S.#	BIDDER NAME & GIST OF COMPLAINTS	DECISION OF CRC
20	**M/S HASSAAN DISTRIBUTION** Tender No.2 (B) SMD0835, 0351, 0008, 1044,& 0350 They submitted their complaint regarding r-check and correction of the typographical error and award product to Glitz Pharma, as they have quoted lowest rates and obtain combined evaluated score lowest rates is from Glitz Pharma show in comparative but there is a company name containing Pharmawise Labs (Pvt) Ltd. instead of Glitz Pharma. **Details of quoted product is as under:** **Item code: SMD0835** Product Description: Povidone Iodine Solution 450ml Competitive Co: M/s. Glitz Pharma Offered Rates: 236.83 M/s. Pharmawise Labs Pvt. Ltd. Offered Rates: 289.00 Remarks: Lowest rates is from M/s. Glitz Pharma shown in comparative statement but there is a company name containing Pharmawise Labs (Pvt) Ltd instead of Glitz Pharma. **Item code: SMD0351** They raised following points regarding the technical and financial qualification of the concerned product for review by the esteemed members of this committee: 1.Qualification based on registration. 2.2. Biocompatibility of Surgery products. 3.Missing marks in the following criterias: CGMP/C.E. + ISO 13485: C.E. & ISO 13485. Valid free sale. Physical examination. **Item code: SMD0008** They raised following points regarding the technical and financial qualification of the concerned product for review by the esteemed members of this committee: Missing marks in the following criterias: 1. CGMP/C.E. + ISO 13485: C.E. & ISO 13485. 2. Valid free sale. 3. Physical examination. 4. Cost effective. **Item code: SMD1044** They raised following points regarding the technical and financial qualification of the concerned product for review by the esteemed members of this committee: 1. Qualification based on registration. 2. 2. Biocompatibility of Surgery products. 3. Missing marks in the following criterias: CGMP/C.E. + ISO 13485: C.E. & ISO 13485.	While reviewing of record and verification of CPC record, CRC observed that grievances of complainant are baseless, hence rejected.

S.#	BIDDER NAME & GIST OF COMPLAINTS	DECISION OF CRC
	4. Valid free sale. 5. Physical examination. **Item code: SMD0350** They raised following points regarding the technical and financial qualification of the concerned product for review by the esteemed members of this committee: 1. Qualification based on registration. 2. 2. Biocompatibility of Surgery products. 3. Missing marks in the following criterias: CGMP/C.E. + ISO 13485: C.E. & ISO 13485. 4. Valid free sale. 5. Physical examination.	

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Health Department.