LEGENDS OF EVALUATION CRITERIA TABLE FOR MEDICAL EQUIPMENTS

The guide which gives short textual information to the reader in interpreting what they see

COLUMN	DESCRIPTION	MARKS	LEGENDS
4	Fully compliance with the required specifications as per Statement of Requirement. Minor deviations may be accommodated up to 3, subject to the condition that main function and performance in any aspect would not be affected. More than 3 minor deviations will be considered as major deviation and the bidder will be considered as non-responsive for the quoted item. (One mark for each deviation will be deducted).	**25**	**F.C.**
5	Certificate of US Food and Drug Administration (USFDA) for the quoted model. 1. Registration if the quoted product belongs to class I. 2. USFDA 510K if the quoted product belongs to class II. 3. Pre-Market approval (PMA) if the quoted product belongs to classIII.	One certificate is mandatory having no marks, while producing other two certificates will get 2 marks each (2+2=4)	C-USFDA
	Certificate of European community (93/42/EEC Medical devices, 98/ 79/ EC In vitro diagnostic medical devices (Full Quality Assurance or Product Quality Assurance or Regulation (EU) 2017/745 on medical devices, Regulation (EU) 2017/ 746 on in vitro diagnostic medical devices and 2014/ 68/ EU Pressure equipment for the quoted product / manufacturer. The certificate must be issued from the European Commission notify bodies.		C-EC
	Certificate of Ministry of health labor and welfare Japan (MHLW) for the quoted model. (Translated English Version)		C-MHLW
6	Valid ISO 13485 Medical Devices Quality Management Systems certificate of manufacturing plant from International Accreditation Forum (IAF) Accredited Bodies.	**3**	ISO-13485
7	Valid ISO 45001 Occupational Health & Safety Certificate of manufacturing plant from International Accreditation Forum (IAF) Accredited Bodies.	**3**	ISO-45001
8	Weightage for local Pakistani original manufacturer.	**3**	LPOM
9	One mark for each after sale satisfactory performance certificate (verifiable) of the firm / bidder in last five years on letter head, signed and stamped letter for the quoted model or previous provided model of equipment from the public sector Performance certificate shall be coupled with supply order / purchase order from public.	**5**	SPC-Pub
10	One mark for each after sale satisfactory performance certificate (verifiable) of the firm / bidder in last six years on letter head for the quoted model or previous provided model of equipment from the teaching level private sector. Performance certificate shall be coupled with supply order / purchase order from teaching level private sector.	**4**	SSPC-Pvt
11	Warranty Period of three (3) years both with spare parts and services from the date of Installation / Commissioning.	**MAND.**	Warranty
12	Diploma of Associate Engineer (DAE) in electrical / electronic / biomedical / mechatronics / mechanical / industrial. DAE certificate must be submitted. (1 mark for each certificate)	**2**	DAE
13	Graduate Engineer with PEC Registration in electrical / electronics, biomedical / mechatronics / mechanical / industrial. PEC registration card of the engineer must be submitted. (1 marks for each Engineer)	**4**	GE-PEC-R
14	Availability of workshop in Khyber Pakhtunkhwa to be verified with Ownership / Rent Agreement with Owner / Rent Agreement with Company Name.	**MAND.**	A-OW-KPK
15	List of related tools available at workshop. Details shall be submitted with technical bid.	**2**	LRT
16	List of Testing and Calibration tools for the quoted items available at workshop. Details shall be submitted with technical bid.	**2**	LTCT
17	Detail of Spare parts availability at workshop for the quoted items. Details shall be submitted with technical bid.	**2**	DSPA
18	Annual Sales tax returns for last two years (1 mark for each year).	**2**	ASTR
19	Annual Income tax returns for last two years (1 mark for each year).	**2**	AITR
20	Last two years Audited Balance Sheet Duly attested by Chartered Accountant (1 mark for each year).	**2**	ABS
21	Firm / bidder registration at relevant forum (SECP/Registrar of Firm/bidder, FBR).	**MAND.**	Bidder Reg.
22	Valid Embassy Attested Authorization	**MAND.**	VECA
23	Firm / bidder registered with DRAP (Drug Regularity Authority of Pakistan) to import / manufacture of medical devices / PEC (Pakistan Engineering Council) in code ME06.	**2**	R-DRAP-ME-06
24	Valid ISO 9001 Quality Management Certificate of the firm / bidder from PNAC accredited bodies.	**3**	ISO-9001