**Medical Teaching Institution Ayub Teaching Hospital (MTI ATH) Abbottabad**

**Technical Evaluation Criteria for Manufacturers of Medical Devices including Cardiothoracic, Gastroenterology, Neurosurgery, Orthopedics, Eye, Cardiovascular Surgery & Urology Implants, Dental Cartridges, Dialysis, TPM Wires, Angiography Material, Surgical Disposables and Sutures for MTI ATH Abbottabad FY 2024-25**

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| **Name of Firm** | | **Factory Technical Evaluation** | **Marks** |
|  | **A. Document based Factory Score** | 1)Valid ISO 14001 certificate of the facility where the quoted product is manufactured, issued by PNAC accredited body (duly attested by the senior executive of the firm) **Online verification link shall be provided** | 05 |
| 2)Valid ISO 17025 certificate of the facility where the quoted product is manufactured, issued by PNAC accredited body (duly attested by the senior executive of the firm) **Online verification link shall be provided** | 05 |
| 3)Valid ISO 9001 certificate of the facility where the quoted product is manufactured, issued by PNAC accredited body (duly attested by the senior executive of the firm)**Online verification link shall be provided** | 05 |
| 4)Valid ISO 45001 certificate of the facility where the quoted product is manufactured, issued by PNAC accredited body (duly attested by the senior executive of the firm) **Online verification link shall be provided** | 05 |
| 5) Valid ISO 13485 certificate of the facility where the quoted product is manufactured, (duly attested by senior executive of the firm). **Online verification link shall be provided** | 05 |
| 6)Valid calibration certificates issued by a firm accredited with PNAC for equipment/instruments used in the factory for measuring, weighing, assay/analysis of raw material, in – process material and finished product for the manufacturing of the quoted products. **Valid calibration certificates attested by quality head of the firm** | 04 |
| 7) Valid documents of the FBR showing the financial turn-over of the firm of the last year. Max 10 marks will be awarded in the following manner  Financial turnover of PKR <100 million 0 marks  Financial turnover of PKR 100 to < 300 million -2 marks  Financial turnover of PKR 300 to < 500 million -4 marks  Financial turnover of PKR 500 to <700 million - 6 marks.  Financial turnover of PKR 700 to <900 million -8 marks.  Financial turnover of PKR 900 million & above -10 marks  **Note:** The documents shall be attested by the senior executive of the firm. | 10 |
| **B. Product Technical Parameters** | 8) Goods Declaration certificate of imported raw material of the quoted item/s from Pakistan Customs. (Certificate Duly attested by Senior Executive of the firm) | 05 |
| 9) Certificate of Analysis of raw material from the Principal Manufacturer as mentioned in the goods declaration (GD) provided in column 14, duly attested by the senior executive of the firm. In case of Non-provision of matching GD the marks for CoA will not be awarded. | 05 |
| 10) Tender Approvals from other Secondary & Tertiary Govt. Hospitals outside Abbottabad or JCI accredited private entities/hospitals of KPK/other provinces of Pakistan. Marks shall be awarded in the following manner:  02 Tender approvals- 01 mark  04 Tender approvals- 02 marks  06 Tender approvals- 03 marks  08 Tender approvals- 04 marks  10 Tender approvals- 05 marks  12 or more Tender approvals- 06 marks  **Note.** Tender approval means award of contract(s) for the Firm/quoted product(s). | 06 |
| 11) Valid product registration with DRAP | 5 |
| 12) Physical examination of the quoted item/s by the expert/. Either of TEC/end user. Non-satisfactory report (<05 marks) may lead to disqualification. | 10 |
| **Total Technical Score (A+B)** | **70** |

**Note:** Minimum qualifying score in technical evaluation is 70% i.e. 49 marks. Total Financial Score is 30 and the Contract shall be awarded to the Best Evaluated Bidder/s; obtaining maximum

accumulative marks in Technical and Financial proposals.

**Member: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Member: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Member: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Chairman: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Hospital Director \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Medical Teaching Institution Ayub Teaching Hospital (MTI ATH) Abbottabad**

**Technical Evaluation Criteria for Importer of Medical Devices including Cardiothoracic, Gastroenterology, Neurosurgery, Orthopedics, Eye, Cardiovascular Surgery & Urology Implants, Dental Cartridges, Dialysis Material, TPM Wires, Angiography Material, Surgical Disposables and Sutures for MTI ATH Abbottabad FY 2024-25**

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| **Description** | | **Evaluation Parameters** | **Marks** |
| **Principal’s and Importers’ Evaluation Parameters** | **A. Principal’s Evaluation** | 1). Valid ISO 14001 certificate issued by authorized body of country of origin duly accredited by with International Accreditation Forum (IAF) and attested by Senior Executive of the firm. | 05 |
| 2) Valid ISO 9001 certificate issued by authorized body of country of origin duly accredited by with International Accreditation Forum (IAF) and attested by Senior Executive of the firm. | 05 |
| 3) Valid ISO 13485 certificate issued by authorized body of country of origin duly accredited by with IAF and duly attested by Senior Executive of the firm. | 05 |
| 4) Valid accreditation of manufacturing unit/relevant section by the US-FDA or WHO or any other Official accreditation body (duly attested by Senior Executive of the firm) | 05 |
| **B) Importer’s Evaluation** | 5) Availability of minimum 40% inventory of the total import of the quoted item/s during last one year (certificate to the effect duly signed by the senior executive of the firm & evaluated by the MTI ATH expert/s. | 05 |
| 6) Adherence to Good storage Practices (GSP) of the finished products (Documentary proof of available facilities) | 05 |
|  | 7) Adequate availability of qualified & relevant Human Resource. Allocation of marks is as follows  Pharmacist (at least 1) =2  Manager/CEO=1  Computer operator= 1  Helpers (min 3) = 1  (Certified by the Senior Executive of Firm and proof in terms of credentials and active bank transactions in form of salary transactions) | 05 |
| 8) Valid documents of the Federal Board of Revenue (FBR) showing the total financial turnover of the firm for the last year. (also to submit in technical bid) Maximum 10 marks shall be awarded in the following manner: (The document shall be attested by a Senior executive of the firm)  Financial turnover of PKR <10 million 0 marks  Financial turnover of PKR 10 to < 30 million -1 marks  Financial turnover of PKR 30 to < 50 million -2 marks  Financial turnover of PKR 50 to <70 million -3 marks.  Financial turnover of PKR 70 to <90 million -4 marks.  Financial turnover of PKR 90 million & above- 5 marks | 05 |
| **Product Technical Evaluation** | 1. **Product Technical Parameters** | 9) Goods Declaration Certificates of imported items from Pakistan custom ll of Lading not older than one year of the last date of bid’s submission. | 05 |
| 10) Certificate of Analysis of finished quoted item/s from Principal Manufacturer (duly attested by Senior Executive of the firm) | 05 |
| 11) Raw material source accredited by WHO/US-FDA/EMA/MHRA/TGA/PMDA. In case Pakistan as an API’s source, current GMP certificate from DRAP Pakistan. | 05 |
| 12) Valid ISO 10993 certificate issued by authorized body of country of origin duly accredited by with IAF and duly attested by Senior Executive of the firm. | 05 |
| 13) Physical examination of the quoted item/s by the expert/. Either of TEC/end user. Non-satisfactory report (<05 marks) may lead to disqualification. | 10 |
| **Total Technical Score (A+B+C)** | | | **70** |

**Note:** Minimum qualifying score in technical evaluation is 70% i.e. 49 marks. Total Financial Score is 30 and the Contract shall be awarded to the Best Evaluated Bidder/s; obtaining maximum accumulative marks in Technical and Financial proposals.

**Member: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Member: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Member: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Chairman: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Hospital Director \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Medical Teaching Institution Ayub Teaching Hospital (MTI ATH) Abbottabad**

**Technical Evaluation Criteria for Importers of Cardiac Stents for MTI ATH Abbottabad FY 2024-25**

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|  | | **Principals and Importer Evaluation Parameters** | **Marks** |
| **Name of Firm** | **A. Principal Manufacturer’s Evaluation** | 1)Valid cGMP / CE Mark / Quality Assurance Certificate/ Quality Control. Certificate/COPP/COMP (attested from the embassy of the country of origin in Pakistan or Pakistani embassy in the country of origin). In case of CE Mark / Quality assurance certificate the certificate shall be issued by conformity assessment bodies enlisted in NANDO database under the relevant European Directive for medical devices of European Union Shall be accepted only. Certificate on company's own letter head shall not be acceptable.  (duly attested by senior executive of the firm).Non provision of the certificate shall lead to disqualification of firm | 05 |
| 2)Valid certification of US Food and Drug Administration (US FDA) of quoted item/s & Valid permission for sale/import of the quoted item/s in the US market (duly attested by senior executive of the firm). Non-provision of any of these certificates shall lead to disqualification of the quoted item/s. | 05 |
| 3) Valid JIS certification of quoted item/s from Japanese Ministry of Health, Labor & Welfare (JMHLW) (duly attested by senior executive of the firm). | 05 |
| Valid ISO 14001 certificate of the facility where the quoted products are manufactured, issued by authorized body of the country of origin duly accredited with International Accreditation Forum (IAF), (duly attested by senior executive of the firm). **Online verification link shall be provided.** | 03 |
| Valid ISO 13485 certificate of the facility where the quoted products are manufactured, issued by authorized body of the country of origin duly accredited with International Accreditation Forum (IAF), (duly attested by senior executive of the firm). **Online verification link shall be provided.** | 03 |
| **B. Importer’s Evaluation** | 4)Availability of minimum 40% inventory of the total import of the quoted item/s during last one year (certificate to the effect duly signed by the senior executive of the firm & evaluated by the TEC expert/s). Non availability of the 40% stock at the warehouse at the time of inspection of the importer shall lead to disqualification of the quoted item/s / firm) | 03 |
| 5) Adherence to Good Storage Practices (GSP) for finished goods storage of the quoted item/s. | 03 |
| 6)Valid documents of the Federal Board of Revenue (FBR) showing the total financial turnover of the firm for the last year. (to submit in technical bid).Maximum 10 marks shall be awarded in the following manner:  Financial turnover of PKR 500 to 700 million - 4 marks  Financial turnover of PKR 701 to 900 million - 6 marks.  Financial turnover of more than PKR 901 million and upto 1000 million - 8 marks.  Financial turnover of more than PKR 1000 million - 10 marks  (The document shall be attested by a Senior executive of the firm) | 10 |
| 7)Adequate availability of qualified, (Presence of Category-A Pharmacist/s is / are mandatory), & relevant Human Resource (Certified by the senior executive of the firm & evaluated / confirmed by MCC expert/s at the time of inspection as non-compliance to this parameter shall lead to disqualification of the firm)..Allocation of marks is as follows  Pharmacist (at least 1) =1 Manager/CEO=1Computer operator= 1Helpers (min 3) =1 | 03 |
|  | **C. Product Technical Parameters** | 9) Goods Declaration certificate of imported finished quoted item/s from Pakistan Customs, (Certificate duly attested by senior executive of the firm | 05 |
| 10)Certificate of Analysis of finished quoted item/s from the Principal Manufacturer as mentioned in the goods declaration (GD) provided in column 12, duly attested by the senior executive of the firm. In case of Non-provision of matching GD the marks for CoA will not be awarded. | 05 |
| 11)Tender Approvals (not older than 2 years) from other Secondary & Tertiary Govt. Hospitals outside Abbottabad or JCI accredited private entities/hospitals of KPK/other provinces of Pakistan. Marks shall be awarded in the following manner:  02 Tender approvals- 01 mark 04 Tender approvals- 02 marks 06 Tender approvals- 03 marks  08 Tender approvals- 04 marks 10 or more Tender approvals- 05 marks  **Note.** Tender approval means award of contract(s) for the quoted product(s) with the same brand name and specifications / strength / dosage form. Moreover, the approval(s) shall be duly attested by the concerned procuring entity/purchasing agency/ies, etc. Copies of the supply orders/purchase orders shall not be considered as tender approval. | 05 |
| 12)Physical examination of the quoted item/s by the expert/. Either of TEC or end user  Rejection of the quoted item/s by the MCC expert/s shall lead to disqualification of the said item/s.). | 15 |
|  |  | **Total Technical Score (A+B+C)** | **70** |

**Note:** Minimum qualifying score in technical evaluation is 70% i.e. 49 marks. Total Financial Score is 30 and the Contract shall be awardedto the Best Evaluated Bidder/s; obtaining maximum accumulative marks in Technical and Financial proposals**.**

**Member: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Member: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Member: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Chairman: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Hospital Director \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**