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PREQUALIFICATION DOCUMENTS

**(DISPOSABLE ITEMS (CATH LAB & ELECTROPHYSIOLOGY DEPARTMENTS)**

## (Original manufacturers/their authorized sole agents/suppliers and in case of imported goods their authorized agents/importers/suppliers in Pakistan)



**(FINANCIAL YEAR 2021-22)**

**RAWALPINDI INSTITUTE OF CARDIOLOGY RAWAL ROAD, RAWALPINDI**

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Prequalification Documents for Disposable Items for Cath Lab & EP Department FY 2021-22

**INVITATION FOR PREQUALIFICATION (2021-22)**

Original **manufacturers/their authorized sole agents/suppliers and**

**in case of imported goods their authorized agents/importers/suppliers in Pakistan**

**REFERENCE NO. RIC/PO/260/21, DATED 13-07-2021**

1. Rawalpindi Institute of Cardiology, Rawal Road, Rawalpindi, invites the eligible bidders (original manufacturers/their authorized sole agents/suppliers and in case of imported goods their authorized agents/importers/suppliers in Pakistan for supply of Goods) for prequalification of medicine

/ drugs.

1. Prequalification shall be conducted as per the procedure specified in the Prequalification Documents.
2. A complete set of original Documents shall be downloaded from [**www.ppra.punjab.gov.pk**](http://www.ppra.punjab.gov.pk/) &

[**www.ric.gop.pk**](http://www.ric.gop.pk/) until the closing date for the submission of documents.

1. Firm shall pay a non-refundable Prequalification fee of **Rs. 1000/-** from the Account office of Rawalpindi Institute of Cardiology, Rawal Road, Rawalpindi after submission of a written application on letter head.
2. **Pre-bid meeting** will be held on **19-07-2021 at 10:00 am** under the chairmanship of Executive Director, Rawalpindi institute of cardiology Rawalpindi. (If any query)
3. Prequalified documents to be submitted by the interested bidders on **27-07-2021 at 11:00 AM** positively in the Purchase Office at Rawalpindi Institute of Cardiology, Rawal Road Rawalpindi. The bids received till the stipulated date & time shall be opened on the same day at **11:30 AM** in the presence of the bidders or their authorized representatives (who choose to attend) by the purchase committee.
4. The Request for Proposals (RFP) will be called only from the Prequalified Firms by the concerned procuring agencies.
5. In an event where the last date for submission of bids be declared a public holiday the due date for submission and opening of bids shall be the following working day at the same appointed timings and venue.

### Note: The procurement shall be governed by the Punjab Procurement Rules, 2014. (amended 2020)

**Executive Director**

**Rawalpindi Institute of Cardiology Rawal Road, Rawalpindi**

**051-9281111-20**

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# GENERAL INSTRUCTIONS

|  |
| --- |
| **A. General** |
| **1. Scope of Applications** | 1.1 | In connection with the *Invitation for Prequalification*, the Procuring Agency, issues this Prequalification Document to |
|  |  | applicants interested in bidding for supply of listed **Disposable** |
|  |  | **Items for Cath Lab & Electrophysiology Department** to be |
|  |  | supplied in different Cardiac Institutes/ Hospitals of the Punjab. |
| **2. Corrupt Practice** | 2.1 | (a) In pursuance of this policy, the following terms are defined: |

* + 1. “Corrupt practice” is the offering, giving, receiving or soliciting, directly or indirectly, of anything of value to influence improperly the actions of another party;

(b)

* + 1. “Fraudulent practice” is any act or omission, including a misrepresentation, that knowingly or recklessly misleads, or attempts to mislead, a party to obtain a financial or other benefit or to avoid an obligation;

(c)

* + 1. “Collusive practice” is an arrangement between two or more parties designed to achieve an improper purpose, including influencing improperly the actions of another party;

(d)

* + 1. “Coercive practice” is impairing or harming, or threatening to impair or harm, directly or indirectly, any party or the property of the party to influence improperly the actions of a party;

(e)

( v ) “obstructive practice” is deliberately destroying, falsifying, altering or concealing of evidence material to the investigation or making false statements to investigators in order to materially impede a Bank investigation into allegations of a corrupt, fraudulent, coercive or collusive practice; and/or threatening, harassing or intimidating any party to prevent it from disclosing its knowledge of matters relevant to the investigation or from pursuing the investigation; or

(f)

1. the Procuring Agency will reject a proposal for award if it determines that the bidder recommended for award has, directly or through an agent, engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for the contract inquestion;

(g)

1. the Procuring Agency will sanction a firm or individual, including declaring ineligible, either indefinitely or for a stated period of time, to be awarded a contract if it, at any time, determines that the firm has, directly or

through an agent, engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for, or in

1. Procuring Agency will have the right to require that a provision be included in bidding documents requiring bidders, suppliers and manufacturers and their agents to permit the Procuring Agency to inspect their accounts and records and other documents relating to the bid submission and contract performance and to have them audited by auditors appointed by the Purchaser;
2. **Eligible Applicants** 3.1 An Applicant can be a private, or public entity, or any

combination of public or private entities.

* 1. Firms of a country may be excluded from bidding if as a matter of law or official regulation, the Government of Pakistan prohibits commercial relations with that country or for other reasons.
	2. A firm declared disqualified / blacklisted by any of the private/public sector organization in Pakistan shall be ineligible to bid for a contract during the period of embargo.
	3. Applicants and all parties constituting the Applicant shall not have a conflict of interest. Applicants shall be considered to have a conflict of interest, if they participated as a consultant in the preparation of the technical specifications of the goods that are the subject of this prequalification. Where a firm, or a firm from the same economic or financial group, in addition to consulting, also has the capability to manufacture or supply goods or to construct works, that firm, or a firm from the same economic or financial group, cannot normally be a supplier of goods or works, if it provided consulting services for the contract corresponding to this prequalification, unless it can be demonstrated that there is not a significant degree of common ownership, influence or control.
	4. The applicants must submit the product (foreign) as per

reference list of manufacturer, annexed or their equivalent.

**B. Contents of the Prequalification Document**

### Sections of Prequalification Document

* 1. The document for prequalification of Applicants (hereinafter

**-**“prequalification document”) consists all the sections indicated below, and should be read in conjunction with any of addendum if issued.

* + - Section I General Instructions
		- Section II Qualification Criteria and Requirements
		- Section III Application Form
		- Section IV Evaluation Criteria
	1. The “Invitation for Prequalification Applications” issued by the Procuring Agency is the part of the prequalification document. A sample form is provided as an attachment to this Prequalification Document.
	2. The Procuring Agency accepts no responsibility for the completeness of the prequalification document and its addenda unless the original receipt of the bank deposit slip is attached with the documents.

### Clarification of Prequalification Document

1. **Amendment of Prequalification Document**
	1. The Applicant is expected to examine all instructions, forms, and terms in the Prequalification Document and to furnish all information or documentation required by the Prequalification Document.

5.1 A prospective Applicant requiring any clarification of the Prequalification Document shall contact the Procuring Agency in writing. The Procuring Agency will respond in writing to any request for clarification provided that such request is received no later than ten (10) days prior to the deadline for submission of applications. The Procuring Agency shall forward copies of its response to all applicants who have acquired the prequalification document directly from the Procuring Agency including a description of the inquiry but without identifying its source. Should the Procuring Agency deem it necessary to amend the prequalification document as a result of a clarification it shall do under intimation to all the applicants who have obtained the prequalification documents

* 1. At any time prior to the deadline for submission of applications, the Procuring Agency may amend the Prequalification Document by issuing addenda.
	2. Any addendum issued shall be part of the Prequalification Document and shall be communicated in writing to all who have obtained the prequalification document from the Procuring Agency.
	3. To give prospective Applicants reasonable time to take an addendum into account in preparing their applications, the Procuring Agency may, at its discretion, extend the deadline for the submission of applications.

**C. Preparation of Application**

1. **Cost of Applications** 7.1 The Applicant shall bear all costs associated with the

preparation and submission of its application. The Procuring Agency will in no case be responsible or liable for those costs, regardless of the conduct or outcome of the prequalification process.

### Language of Application

1. **Documents Comprising the Application**
2. **Application Submission Form**
3. **Documents Establishing the Eligibility of the Applicant**
4. **Documents Establishing the Qualifications of the Applicant**

8.1 The application as well as all correspondence and documents relating to the prequalification exchanged by the Applicant and the Procuring Agency, shall be written in the English language. Supporting documents and printed literature that are part of the application may be in another language, provided they are accompanied by an accurate translation of the relevant passages in the English language, in which case, for purposes of interpretation of the application, the translation shall govern. All such documents should be signed and stamped by the applicant.

* 1. The application shall comprise the following;
		1. Application Submission Form;
		2. documentary evidence establishing the Applicant’s eligibility to prequalify;
		3. documentary evidence establishing the Applicant’s qualifications; and
		4. any other document required as specified in the documents
		5. Supplier’s Declaration
		6. Foreign and/ or Local Manufacturer’s Declaration
		7. Comprehensive Data Sheet

10.1 The Applicant shall prepare an Application using the form provided in the documents. This Form must be completed without any alteration to its format.

11.1 To establish its eligibility, the Applicant shall complete the Declarations for the Supplier and Principal firm/ manufacturer along with other documents mentioned in the Pre-Qualification Form.

12.1 To establish its qualifications to perform the contract in accordance with concerned Sections, Qualification Criteria and Requirements, the Applicant shall provide the information requested as evidence to comply with the criteria.

### Signing of the Application

13.1 The application shall be typed or written in indelible ink and shall be signed by a person duly authorized to sign on behalf of the Applicant.

##  D. Submission of Application

### Sealing and Identification of Applications

1. **Deadline for Submission of Applications**
	1. The Applicant shall enclose the original application in a sealed envelope that shall:
		1. bear the name and address of the Applicant;
		2. be addressed to the Procuring Agency; and
		3. bear the specific identification of this prequalification process indicated in the documents
	2. Applicants will submit their applications by hand. Applications shall be received by the SPECIALIZED HEALTHCARE & MEDICAL EDUCATION DEPARTMENT at the address and no later than the deadline indicated in the **Invitation for Prequalification.**
	3. The Procuring Agency may, at its discretion, extend the deadline for the submission of applications by amending the Prequalification Document in which case all rights and obligations of the Procuring Agency and the Applicants subject to the previous deadline shall thereafter be subject to the deadline as extended.
2. **Late Applications** 16.1 Any application received by the Procuring Agency after the

deadline for submission of applications will not be entertained.

### Opening of Applications

* 1. The Procuring Agency shall open all Applications at the date, time and place as specified. Late Applications shall not be accepted.
	2. Procuring Agency shall prepare a record of the opening of applications that shall include the name and other details of the Applicant.

**E. Procedures for Evaluation of Applications**

1. **Confidentiality** 18.1 Information relating to the evaluation of applications, and

recommendation for prequalification, shall not be disclosed to Applicants or any other persons not officially concerned with such process until the notification of prequalification is made to all Applicants.

18.2 From the deadline for submission of applications to the time of notification of the results of the prequalification, any Applicant that wishes to contact the Procuring Agency on any matter related to the prequalification process, may do so but only in writing.

1. **Clarification of Applications**
	1. To assist in the evaluation of applications, the Procuring Agency may, at its discretion, ask any Applicant for a clarification of its application which shall be submitted within a stated reasonable period of time. Any request for clarification and all clarifications shall be in writing.
	2. If an Applicant does not provide clarifications of the information requested by the deadline, the application shall be evaluated based on the information and documents available at the time of evaluation of the application.
2. **Responsiveness of Applications**

20.1 All applications not responsive to the requirements of the prequalification document shall be rejected.

**F. Evaluation of Applications and Prequalification of Applicants**

1. **Evaluation of Applications**
	1. The Procuring Agency shall use the factors, methods, criteria, and requirements defined in Evaluation Criteria and Requirements to evaluate the qualifications of the Applicants.
	2. Physical Verification of data contained in the application will be conducted by an Inspection Team. The firm will not be considered, if found variation between submitted data and on grounds reality.
2. **Procuring Agency’s Right to Accept or Reject Applications**
	1. The Procuring Agency reserves the right to accept or reject all the applications, and to annul the prequalification process, without thereby incurring any liability to Applicants as per PPRA 2014.
	2. After pre-qualification, the Department may review the pre- qualification of any firm on some serious complaints and terminate the status, if proved.
3. **Prequalification of Applicants**

23.1 The Applicants whose applications have met the specified requirements will, to the exclusion of all others, be prequalified by the Procuring Agency.

1. **Notification of Prequalification**
	1. Once the Procuring Agency has completed the evaluation of the applications it shall notify all Applicants in writing indicating their status as to qualified or ineligible.

|  |  |  |
| --- | --- | --- |
|  | 24.2 | The pre-qualification shall be awarded on individual item basis |
|  | with manufacturer which is contained in the attached list |
| **25. Invitation to Bid** | 25.1 | After notification of the results of the prequalification, the |
|  |  | Procuring Agency shall initiate the procurement process and |
|  |  | issue the Bidding Documents to the pre-qualified firms for |
|  |  | further process of purchase. |
| **26. Arbitration** | 26.1 | Secretary, SH&ME Department Government of the Punjab willbe the Arbitrator. The decision of the Arbitrator will be final and binding on the applicant applying for prequalification |

## Annex I

### PREQUALIFICATION FORM

**PRE-QUALIFICATION OF FIRM / AGENT**

Product applied for (S.No. and name of item)\_ Name of firm

Address Phone Fax E-mail URL [http://www.](http://www/)

Type of firm:

Sole Proprietor

Partner Ship

Limited

Other Date of establishment \_

List of Board of Directors, Partners, Key Management Personnel (both Technical, Sales &Management - include position, professional qualification, experience).

Total area of the firm premises

Owned

Rented

Total no. of Employees: Technical Non – Technical National Tax Number Date

General Tax Number Date Registrations / Prequalification with other departments:

### Detail of Head / Branch Office / Workshop (s):

Address: Phone Fax Address Phone Fax

Annual business turnover, last 3 years (Rs.)

Annual Income tax paid, last 3 years (Rs.)

### Main Contracts during last three years:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **S.No.** | **Name of Item** | **Name of Manufacturer** | **Quantity** | **Year** | **Institution** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

**Sales / Marketing Staff:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Name** | **Designation / Responsibility** | **Qualification** | **Total Experience** | **Experience with Current Firm** | **Training Detail (Local &abroad)** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

**Technical Staff:** (Production & Backup Services staff; in case of local manufacturer)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Name** | **Designation /****Responsibility** | **Qualification** | **Total****Experience** | **Experience with****Current Firm** | **Training Detail****(Local &abroad)** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

**Note: The Human Resource list will be verified from the Bank Salary/ Account for authenticity.**

Major Testing / Calibration / Repair Tools (for specific item as per attached

**Note: The Local manufacturer will give the detail of their production machinery.**

Arbitration History (if any):

Name & Capacity of the Authorized Contact Person: Signature of the Authorized Contact Person:

Date: Stamp of the Firm:

### DOCUMENTS TO BE ATTACHED (COPIES):

* + 1. Organizational Chart showing chain of command.
		2. Valid **Sole** agency agreement (s) preferably attested by the Embassy Concerned
		3. NTN Certificate and GST Certificate
		4. Registration / Pre-qualification with other departments.
		5. ISO 9001:2008 certificate, if available.
		6. References from existing Customers.
		7. Documents and necessary certificates to establish the equivalent brand, in case that manufacturer is not included in the reference manufacturer’s list.
		8. Other documents as a proof to comply with the qualification criteria and requirements.
		9. Copy of FDA Certificate from manufacturer or as mentioned in Specs. (it is mandatory that the product must bear FDA certification).

**NOTE**: The Original “FOREIGN MANUFACTURER DECLARATION” as per annex III, must be available during physical inspection/ verification of the sole agent, if applicable.

## Annex II SUPPLIER DECLARATION

(on letter head of the applicant)

To Dated:

### The Executive Director Rawalpindi Institute of Cardiology Rawalpindi.

I declare that:

* I am authorized to represent the Firm specified in this prequalification application as the "Firm" for the purpose of prequalification of equipment for the following items out of the specified equipment list;

|  |  |
| --- | --- |
| **S.No. in the list** | **Name of the equipment** |
|  |  |
|  |  |
|  |  |

* I am the **Sole** distributor/agent/ partner of M/s [*name of the principal (s)*] for the last [*numbers*] years.
* All the information provided in this application is current and correct and the firm has no reservations with the Pre-Qualification Documents.
* This application contains all the information as is prescribed in the *Prequalification Document*.
* The Firm will abide by all the rules and regulations, formulated by the government of Punjab, Specialized Healthcare & Medical Education Department.
* The firm will notify you of all changes and variations to the Product / its manufacturing status.
* The firm has not been declared ineligible/blacklisted by any Government/ Semi Government Department or Private Organization.
* If the Firm does not abide by the above stated Declaration then the Government of Punjab has every right to Blacklist the Firm.

Name of the Firm: Name & capacity of the Authorized Contact Person: Signature of the Authorized Contact Person:

Date: Stamp of the Firm:

## Annex-III

**FOREIGN MANUFACTURER DECLARATION**

(on letter head of the manufacturer)

To Dated:

### The Executive Director Rawalpindi Institute of Cardiology Rawalpindi.

I declare that:

* I am authorized to represent [ name of the manufacturer] as the "Manufacturer" for the purpose of prequalification of equipment for the following items out of the specified equipment list;

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **S.No. in the list** | **Name of the equipment** | **Production Country** | **Production Capacity** | **Quality Standard Compliance** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

Note: Please attach the Certificates of Quality Standards’ compliance issued by the notified bodies.

* M/s [*name of the existing distributor*] is our **Sole** [distributor/agent/ partner] for the last [*numbers*] years.
* The Firm will abide by all the rules and regulations, formulated by the Government of the Punjab, Specialized Healthcare & Medical Education Department, Pakistan.
* The firm will notify all changes and variations to the Product/ its manufacturing status/ change of **Sole** distributor/agent/ partner.
* The firm confirms the availability of spare parts for at least 10 years
* The firm takes the responsibility to fulfill all warranty & service contract related commitments, by themselves or through another supplier /distributor/ partner in case existing is changed.
* The firm has not been declared ineligible/blacklisted by any Government/ Semi Government Department or Private organization.
* All the information provided in pursuance with this declaration is current and correct*.*

Name and Capacity of the Authorized Contact Person: Signature of the Authorized Contact Person:

Date: Stamp of the Firm:

## Annex V

**EVALUATION CRITERIA**

The Evaluation Criteria comprises of two parts first part is the KNOCKDOWN while the second is weighted.

### PART-1: KNOCK DOWN

**The firm has to comply all of the following parameters, otherwise it will be knocked down and made ineligible for further processing.**

***COMPULSORY PARAMETERS***

1. *Original tender purchase receipt.*
2. *Valid NTN and GST registration certificate.*
3. *The Firm must submit valid Drug Sale License, if applicable.*
4. *In case of manufacturer / subsidiary of foreign manufacturer / sole agent of foreign manufacturer, the bidder must submit the valid sole Agency Agreement / relevant certificate issued by the foreign principals (translated in English).*
5. *The Applicant/ Firm will provide valid Medical Devices Registration Certificate of the quoted product issued by DRAP.*
6. *The quoted product must have at least one year market experience.*
7. *In case of manufacturer /subsidiary of foreign manufacturer / sole agent of foreign manufacturer, the storage condition of local warehouse and logistics facilities must fulfill the conditions prescribed by the DRAP / concerned regulatory authority. Evidence to be provided by the bidder to establish efficacy. Technical Evaluation Committee may physically inspect the offices / premises / warehouses.*
8. *The bidder must undertake on stamp paper that firm is not black listed / debarred by any procuring agency, neither the firm is involved in any litigation against the Government organization against the black listing order.*
9. *The bidder shall provide the copy of valid free sale certificate / relevant Quality certificate issued by the manufacturer or regulatory authority of the concerned country of origin.*

**EVALUATION CRITERIA (cont)**

**PART-2:** **WEIGHTED** (65% MARKS ARE MANDATORY FOR PRE QUALIFICATION)

**MARKING CRITERIA**

|  |  |  |  |
| --- | --- | --- | --- |
| **SERIAL NO.** | **DESCRIPTION** | **CATEGORY****POINTS** | **GRAND TOTAL** |
| **1** | **Bidder Experience (Business)** |  | **20** |
| From 1-2 years | 13 |
| More than 2 and up to 5 years | 15 |
| More than 5years | 20 |
|  | **FINANCIAL CAPACITY OF THE BIDDER** |  |  |
|  | **Annual Turnover of last financial year (***The bidder will* |  |
|  | *provide requisite documents i.e. Federal Board of Revenue* |  |
|  | *document showing the annual turnover/sale of the firm.). In* |  |
|  | *PKR.* |  |
| **3** | **Firms Turnover (For Cardiology & Electrophysiology Items)**Above 200 Million | 20 | **30** |
|  | More than 150 Million and upto 200 Million | 16 |  |
|  | 100 - 150 Million Or Less | 12 |  |
|  | Tax Return (3 years) | 5 |  |
|  | Bank’s Financial Standing Certificate (Proportionate) | 3 |  |
|  | Audited Accounts 3 years | 2 |  |
| **4** | **Past performance of the bidder (execution of** **supply order) w.r.t quoted product i.e. goods supplied within****prescribed delivery period.** |  | **10** |
| Certificate (issued by Head of Institutions) from any public sector cardiac institution / cardiac units in tertiary carehospital / private cardiac hospital. | 5/each |
| **5** | Storage Facility as per DRAP Recommendations orManufacturer |  | **10** |
| **6** | Backup Inventory |  | **5** |
| **7** | Management Systems (Service records/ Installed basemanagement / others) in Place |  | **5** |
| **8** | Support Structure |  | **10** |
| **9** | ISO Certification | ISO 9001-2008/2015 | **10** |
|  | **GRAND TOTAL** |  | **100** |
|  | **QUALIFYING MARKS = 65 %** |  |  |

**Note:** The Technical staff / Human Resource list will be verified from the Bank Salary/ Account for authenticity. Evidence of same to be submitted along with the list of staff.

### Annexure-VII

**LIST OF DISPOSABLE ITEMS FOR CATH LAB AND ELECTROPHYSIOLOGY DEPARTMENTS FOR THE FY. 2021-22**

|  |  |  |
| --- | --- | --- |
| **S #** | **DETAIL** | **SPEC** |
|  | **Coronary** |  |
| 1 | Coronary covered stent (single stent design) | No |
| 2 | Japanese /US coronary Semi complaint / complaint Balloons with FDA approvalincluding 1.2mm diamater | No |
| 3 | European semi compliant / compliant balloons with European CE mark including 1.2mm diamater | No |
| 4 | Japanese / US coronary Non-complaint Balloons with FDA approval | No |
| 5 | European non-compliant balloons with European CE mark | No |
| 6 | Coronary over the wire balloon | No |
| 7 | Coronary Drug Coated balloon (DCB)with evidence of randomize control trials | No |
| 8 | Cutting Balloon All sizes | No |
| 9 | Dilatation Catheter O.P.N.C with inflation gun or equivalent | No |
| 10 | Inflation Device with accessories | No |
| 11 | Mani fold 3 port | No |
| 12 | Y-Hemostasis valve set (click system) 6 & 8f | No |
| 13 | Pressure tube 150cm (for manifold) | No |
| 14 | Radial Sheaths All Sizes | No |
| 15 | M Coat Radial Sheath | No |
| 16 | Cylinder radial sheath 6 in 7 | No |
| 17 | Femoral Sheaths all sizes | No |
| 18 | Femoral Sheaths 9 to 10 F | No |
| 19 | EnSnare Catheter (3loop) | No |
| 20 | Pressure Wire | No |
| 21 | Eagle Eye Platinum IVUS Catheter | No |
| 22 | Fast view Imaging Catheter | No |
| 23 | Japenese/US FDA approved Coronary Aspiration Catheter | No |
| 24 | PTCA GUIDE Catheter All shapes & Sizes (US FDA Approved) | No |
| 25 | Diagnostic Catheter All shapes & Sizes (US FDA Approved) | No |
| 26 | Radial Tiger 1 Diagnostic catheter | No |
| 27 | Japenese/US FDA approved Diagnostic Catheter Vert 125cm | No |
| 28 | Japenese/US FDA approved Diagnostic Catheter Sim 2 | No |
| 29 | Japenese/US FDA approved Diagnostic Catheter VTK 125cm | No |
| 30 | Rota Wire | No |
| 31 | Rota Link Plus (All Sizes) | No |
| 32 | Coronary Micro Catheter Torqbale, tapered septal dilator, longest length | No |
| 33 | Dual LeumanMicrocatheter | No |
| 34 | Coronary Micro Catheter non tapered | No |
| 35 | Angled Coronary Microcatheter | No |
| 36 | Guide Catheter Extention | No |
| 37 | Glide wire angled hydrophilic coating 0.035 x 260cm | No |
| 38 | Exchange wire normal 260cm |  |
| 39 | Souh PCI Wire or equivalent | No |
| 40 | Coronary Worhorse Wire US FDA Approved | No |
| 41 | PTCA Guide wire pilot 50 or equivalent | No |
| 42 | PTCA Guide wire pilot 200 or equivalent | No |
| 43 | PTCA Guide wire Fielder XT or equivalent | No |
| 44 | PTCA Guide wire Sion or equivalent |  |
| 45 | PTCA Guide wire RG3 or equivalent | No |
| 46 | PTCA Guide wire Confianza Pro 12 or progress 200-T or equivalent | No |
| 47 | PTCA Guide wire Gaia or equivalent | No |

|  |  |  |
| --- | --- | --- |
| 48 | PTCA Guide wire Grand Slam or BHW or equivalent | No |
| 49 | Tr Band | No |
| 50 | Femoral closure Device Angiosel or equivalent | No |
| 51 | Femoral closure Device Proglide or equivalent | No |
| 52 | Concerto Microcoils for Septal Perforation 0.014 or Equivalent | No |
| 53 | PTMC Balloon Innoue or Equivalent US FDA Approved | No |
| 54 | Mullen Sheath or equivalent | No |
| 55 | Transeptal Needle |  |
| 56 | Borekenbrough transseptal Catheter |  |
| 57 | 0.032 J Tip 150cm Guide Wire |  |
| 58 | Angioplasty Drap Set | No |
| 59 | Disposable Surgical Gown |  |
| 60 | TAVI Valvue with accessories |  |
| 61 | Introducer Sheath 28cm 14, 18 & 20f | No |
| 62 | Pre Looped Super stiff guide wire | No |
| 63 | Aortic Valvuplastry Balloons | No |
| 64 | Vascular Dilators 12, 14 and 16f | No |
|  | **Peripheral** |  |
| 65 | Japanese/US FDA approved Radifocus Guide Wire M Stiff tip Angled 0.035 x 260or equivalent | No |
| 66 | US FDA approved Peripheral work horse Wire 0.014” | No |
| 67 | US FDA approved Peripheral PTCA Balloon 0.035 System OTW (longest shaftlength) | No |
| 68 | US FDA approved Peripheral PTCA Balloon 0.014 System OTW (longest shaftlength) | No |
| 69 | US FDA approved Peripheral Balloon Expandable Stents OTW 0.035 (longestshaft length) | No |
| 70 | US FDA approved Renal Stent 0.014 | No |
| 71 | US FDA approved Self Expending Stent for Limbs longest shaft length OTW0.035 | No |
| 72 | US FDA approved Peripheral Graft Stent | No |
| 73 | US FDA approved Peripheral infusion catheter longest Length or equivalent | No |
| 74 | US FDA approved 0.014 / 0.035 Peripheral Suppport Catheter | No |
| 75 | Japenese/US FDA approved Peripheral Micro Catheter inner lumen 0.027" | No |
| 76 | US FDA approved Uterine fibrord embolization particles | No |
| 77 | US FDA approved Pushable coils 0.018" | No |
| 78 | Torque device 0.035" | No |
| 79 | Japanese/US FDA approved 4fr Micro Puncture kit | No |
| 80 | Japanese/US FDA approved Destination Sheath or equivalent all sizes | No |
| 81 | Angiojet Catheter Coronary | No |
| 82 | Angiojet Catheter peripheral arterial | No |
| 83 | Jet stream Catheter or equivalent | No |
| 84 | US FDA approved Reterivable IVC Filter with legs (non Cage design) | No |
| 85 | US FDA approved IVC Filter Retriver Kit | No |
| 86 | Femoral Sheath 16F 45CM | No |
| 87 | Femoral Sheath 9F 55 or 65CM | No |
|  | **Neuro intervention** |  |
| 88 | Neuro Aspiration / Support Catheter 6F | No |
| 89 | Stent Retriever Perametric Desgin | No |
| 90 | Micro Catheter Longest Length for stent Retriever | No |
| 91 | Neuro intervention workhorse wire | No |
| 92 | Self-Expanding Carotid Stent closed cell design | No |
| 93 | 0.014 balloons in 5, 5.5 and 6mm diameters in 20mm length | No |
| 94 | Carotid Filter covering vesal diameters including 7mm (wire mounted) | No |
| 95 | Carotid Filter covering vesal diameters including 7mm (wire free filter) | No |
| 96 | Carotid proximal protection device Moma or Equivalent | No |

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| 97 | Guide Sheath 6F For neuroinervention | No |
| 98 | Balloon Tip Guide Catheter 9f | No |
| 99 | US FDA approved Guide Catheter Multipurpose 8F | No |
|  | **PEADS** |  |
| 100 | ASD Device with delivery sytem European CE Mark | No |
| 101 | ASD Device with delivery sytem chinese CE Mark |  |
| 102 | PDA Device with delivery sytem European CE Mark | No |
| 103 | PDA Device with delivery sytem chinese CE Mark |  |
| 104 | Diagnostic Catheter for Peads all sizes |  |
| 105 | Balloon Sizing | No |
| 106 | Glide Wire 0.21 x 260 | No |
| 107 | Amplatz Wires Super Stiff 0.035 | No |
| 108 | Amplatz Wires Extra Stiff 0.035 | No |
| 109 | Velvoplasty Balloon (low profile) | No |
| 110 | Velvoplasty Balloon (heigh profile) | No |
| 111 | VSD Device | No |
| 112 | Amplatz Wires 0.18 | No |
| 113 | Glide Wire 0.25 | No |
| 114 | Bib Balloon | No |
| 115 | Sepostemy Balloon | No |
| 116 | EA Stent | No |
| 117 | PFM Coil or equivalent | No |
| 118 | Aneurysmal VSD Device or Equivalent | No |
| 119 | Infantile VSD Device or Equivalent | No |
| 120 | Tubular PDA Device | No |
| 121 | Wedge Pressure Catheter or Equivalent | No |
|  | **ELECTROPHYSIOLOGY (EP)** |  |
| 122 | T.P.M Lead 5 & 6F | No |
| 123 | PPM Single Chamber or Equivalent (VVIR) | No |
| 124 | Full Body Safe Latest Single Chamber Permanent Pacemaker (VVIR) (orequivalent) ESSENTIO VR EL MRI Pacing System | No |
| 125 | PPM Dual Chamber | No |
| 126 | PPM Dual Chamber (MRI Conditional 1.5T) | No |
| 127 | PPM Dual Chamber (MRI full body safe 3T) – Latest model, not older than 5 yearssince FDA approval) | No |
| 128 | ICD Single or VIGILANT EL ICD (or equivalent) | No |
| 129 | ICD Double or VIGILANT EL ICD (or equivalent) | No |
| 130 | CRT-P or VISIONIST X4 CRT-P complete set (or equivalent) | No |
| 131 | CRT-D or VIGILANT X4 CRT-D complete set (or equivalent) | No |
| 132 | Subcutaneous ICD complete set |  |
| 133 | His bundle pacing with dual IPG (complete set) | No |
| 134 | His bundle pacing ventricular (his) lead with delivery sheath |  |
| 135 | Quadripolar LV lead for CRT with delivery sheath |  |
| 136 | Coronary sinus venogram balloon | No |
| 137 | Implantable Loop Recorders (Linq or DX or equivalent) | No |
| 138 | Cryoballoon set or Equivalent (compatible with cryoconsole) | Set |
| 139 | Cryoballoon only (compatible with cryoconsole) |  |
| 140 | Flexcath Steerable transeptal sheath for Cryoballoon delivery or equivalent(compatible with cryoconsole) |  |
| 141 | Achieve (multipolar) mapping catheter or equivalent (compatible withcryoconsole) |  |
| 142 | Cryofreeze Focal Ablation Catheter (compatible with cryoconsole) | Set |
| 143 | 7 Fr Femoral Sheath | No |
| 144 | 7 Fr Introducer with Peelable Long Sheath (23cm) | No |
| 145 | Disposable chlorhexidine scrub stick e.g. chloraprep (or equivalent) | No |
| 146 | Disposable Drape set for Pacing | No |

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| 147 | Disposable Drape set for EP Study | No |
| 148 | Blazer Prime XP Temperature Ablation Catheter or equivalent | No |
| 149 | Blazer Prime Temperature Ablation Catheter or equivalent | No |
| 150 | Blazer II XP Temperature Ablation Catheter | No |
| 151 | Blazer II HTD Temperature Ablation Catheter, 4mm tip Standard curve (orequivalent) | No |
| 152 | Blazer II Temperature Ablation Catheter Standard (or equivalent) | No |
| 153 | Blazer II Temperature Ablation Catheter Standard Asymmetric Curve (orequivalent) | No |
| 154 | Blazer II Temperature Ablation Catheter Large Curve (or equivalent) | No |
| 155 | Blazer II Temperature Ablation Catheter Large Curve Medium Distal (orequivalent) | No |
| 156 | Blazer II Temperature Ablation Catheter ) Standard Curve, Medium Distal (orequivalent) | No |
| 157 | Blazer II Temperature Ablation Catheter Standard Curve, Extended Distal (orequivalent) | No |
| 158 | Cable, Thermistor For Blazer Ablation Catheters | No |
| 159 | Cable, Recorder-APM (POD to Junction Box IEGM cable) | No |
| 160 | Blazer Open-Irrigated Ablation Catheter Large curve (or equivalent) | No |
| 161 | Cable, Blazer OI to Maestro POD | No |
| 162 | Blazer DX-20 7F Bidirectional Duodecapolar Diagnostic Catheter (or equivalent) | No |
| 163 | Cable, Blazer DX Duodecapolar Catheter (or equivalent) | No |
| 164 | Orbiter ST 7F Steerable Diagnostic Catheter, Duodecapolar (or equivalent) | No |
| 165 | Protected 24-pin Orbiter STTM cable 120cm | No |
| 166 | Polaris X™ Steerable Decapolar Catheter 2.5,5,2.5mm (or equivalent) | No |
| 167 | Polaris X™ Steerable Decapolar Catheters 2,10,2mm (or equivalent) | No |
| 168 | 10-pole male Quick Connect to 10 pins 2mm 5 ft. (or equivalent) | No |
| 169 | Dyn XT 6F Steerable Catheter,110cm,LrgCrv,10E,2,5,2mm (or equivalent) | No |
| 170 | Dyn XT 6F Steerable Catheter (Quadripolar, Hexapolar, Octapolar) with differentspacing (or equivalent) | No |
| 171 | Quadripolar steerable diagnostic EP catheter Dynamic Tip (or equivalent) | No |
| 172 | WovenSp 6F Fixed Curve Catheter, Cournand,5E,10,10,267mm,120cm 120cm,(orequivalent) | No |
| 173 | Woven 6F Fixed Curve Diagnostic Catheter Josephson,,4E,2,5,2mm,125cm (orequivalent) | No |
| 174 | Viking 6F Fixed Curve Diagnostic Catheter Hisser,4E,2,5,2mm,115cms (orequivalent) | No |
| 175 | Viking 6F Fixed Curve Diagnostic Catheter Josephson,4E,2,5,2mm,115cm (orequivalent) | No |
| 176 | Viking 6F Fixed Curve Diagnostic Catheter Cournand,4E,2,5,2mm,115cm (orequivalent) | No |
| 177 | Viking 6F Fixed Curve Diagnostic Catheter Cournand, 4E, 10,10,10mm, 115cm (orequivalent) | No |
| 178 | Viking 5F Fixed Curve Diagnostic Catheter Josephson,4E,2,5,2mm,115cm (orequivalent) | No |
| 179 | Viking 5F Fixed Curve Diagnostic Catheter Hisser,4E,2,5,2mm, 115cm (orequivalent) | No |
| 180 | Viking 5F Fixed Curve Diagnostic Catheter CS,10E,2,5,2mm, 115cm (orequivalent) | No |
| 181 | Cable, Protected 4-Pin,125cms (or equivalent) | No |
| 182 | Cable, Easy-Mate 4-Pin,125cm (or equivalent) | No |
| 183 | Cable, Protected 6-Pin Easy-Mate,125cm (or equivalent) | No |
| 184 | Cable, 10-Pin Surelink,120cm (or equivalent) | No |
| 185 | Cable, Protected 4-Pin Surelink,120cm (or equivalent) | No |
| 186 | Cable, Protected 4-Pin Surelink,120cm Red, Blue,Yellow (or equivalent) | No |
| 187 | Zurpaz 8.5F Bidirectional Steerable Sheath, Symmetric (or equivalent) | No |
| 188 | TSXFS Fixed Sheath 8.5F, 60cm, All Curves (or equivalent) | No |

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| 189 | TSX Transseptal Needle 18GA, 71cm, LrgCrv (or equivalent) | No |
| 190 | TSXFS Fixed Sheath 8.5F, 79.4cm, 55Crv (or equivalent) | No |
| 191 | TSX Transseptal Needle 18GA, 89cm, LrgCrv (or equivalent) | No |
| 192 | SL1 Transeptal long sheath (or equivalent) TSXFS Fixed Sheath 8.5F, 60cm | No |
| 193 | BRK Needle (or equivalent) TSX Transseptal Needle 18GA, 71cm, Standard | No |
| 194 | Safesept needle for transeptal puncture (or equivalent) |  |
| 195 | Valleylab Ground Pad Pack (1x50) (or equivalent) | No |
| 196 | Needle eye snare (for percutaneous lead extraction) | No |
| 197 | Prolene 2-0, straight needle, rounded | No |
| 198 | Open-Irrigated Tubing Kit MetriQ | No |
| 199 | mechanical lead extraction sheath (tightrail or siterail or equivalent) | No |
| 200 | Superior vena cava occlusion balloon. | No |
| 201 | 3D Navigational multipolar catheter lasso (or equivalent) | No |
| 202 | 3D Navigational, Thermocool Smart touch Unidirectional catheter (or equivalent) | No |
| 203 | 3D Navigational multipolar catheter Pentaray (or equivalent) | No |
| 204 | Smartablate System irrigation tubing set (or equivalent) | No |
| 205 | 3D Navigational, Thermocool Navstar Catheter (or equivalent) | No |
| 206 | Cable for multipolar lasso catheter | No |
| 207 | Cable for thermocool smart touch catheter | No |
| 208 | Cable for thermocool navstar catheter | No |
| 209 | Cable for multipolar pentaray catheter | No |
| 210 | 3D mapping external reference patch | No |
| 211 | Ground patch compatible with 3D mapping ablation PIU | No |
| 212 | Defibrillator patches (compatible with hospital defibrillator) |  |
| 213 | Intracardiac echo (ICE) catheter (e.g. accunav) or equivalent compatible with ICEconsole |  |
| 214 | Percutaneous Left Atrial Appendage Occlusion Device (e.g. watchman) orequivalent |  |
| 215 | Bioptome for Myocardial Biopsy |  |

Page **23** of **23**

## Annex-VIII

**COMPREHENSIVE DATA SHEET**

**NAME OF THE FIRM *\_\_\_\_***  ***\_***  ***\_***  **Dated:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **ITEM NO. MENTIONED IN THE LIST OF REQUIRED EQUIPMENT** | **ITEM NAME** | **EQUIPMENT CAPABILITY** | **TOTAL NUMBER OF REGULAR TECHNICAL STAFF (GRADUATE AND DAE ONLY)** | **TECHNICAL & MANAGERIAL CAPABILITY** | **SPECIFIC CALIBERA TION TOOL** | **MAJOR CLIENT OF THIS ITEM** |
| **NUMBER OF REGULAR SPECIALIST DEPUTED FOR THE PRODUCT** | **NAME OF THE SPECIALIST(S) FOR THE ITEM** | **QUALIFIC ATION** | **TOTAL EXPERIEN CE** | **EXPERIENC E WITH CURRENT FIRM** |
| **NAME OF THE MANUFAC TURER** | **ORIGIN OF MANUFACT URER** | **COUNTRY OF MANUFACTUR ING UNIT** | **PRODUCTIO N CAPACITY (PER MONTH)** | **QUALITY STANDARD S COMPLIAN CE** | **QUANTITY SOLD IN PAKISTAN DURING LAST****THREE YEARS** |
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Name and Capacity of the Authorized Contact Person: Signature of the Authorized Contact Person:

Stamp of the Firm: