# ALL INDIA INSTITUTE OF MEDICAL SCIENCES ANSARI NAGAR, NEW DELHI-29 STORES SECTION (DO)

Ref. No. 11/Stores(DO)/E.M./PAC/2020-21/FSC-I

Dated- 07/04/2021

Sub:- Purchase of "Wound Management Device – 02 Nos. for the Department of Emergency Medicine, at AIIMS, New Delhi-110029, on proprietary basis Inviting comments thereon.

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The Institute is in the process to purchase "Wound Management Device – 02 Nos." for the department of Emergency Medicine at AllMS, New Delhi from M/s. KCI, USA Inc. through M/s. Nanak Enterprises. The PAC Certifications by M/s. KCI, USA Inc. as well as the user department are attached.

The above documents are being uploaded for open information to submit objections, comments, if any, from any manufacturer regarding proprietary nature of the equipment/item within 15 day from the date of issue/uploading of the notification giving reference No. 11/Stores(DO)/E.M./PAC/2020-21/FSC. The comments should be received in office of Stores Officer (FSC), Store Section (DO), Animal House Building, Near Biotechnology Building at AIIMS on or before 26/04/2021 upto12.30 p.m. failing which it will be presumed that any other vendor is having no comment to offer and case will be decided on merits.

Yours faithfully,

SR. STORES OFFICER (DO)

Encl: Related documents enclosed.



Quantity-2Nos.

App: 30 Lakh

- 1. It should be capable of providing Negative Pressure Wound Therapy to multiple wounds simultaneously with individual channel controls and feedback
- 2. It should have 4 separate channels with separate individual settings -individual pressure, intensity and mode can be assigned at the same time
- 3. It should hold 4 separate individual Canister at a time and should have separate individual canister release buttons
- 4. It should have start, stop and pause buttons for individual channels
- 5. It should have continuous and intermittent mode
- 6. It should provide controlled, localized sub-atmospheric pressure in continuous or intermittent mode to help draw wounds closed allowing tissue decompression and enhanced blood flow
- 7. It should be compatible with soft open cell reticulated polyurethane foams with pore size 400-600 microns.
- 8. The system should be able, to be used on heavily exudating wounds of various sizes and shapes to deal with like burns, trauma wounds, chronic wounds, diabetic foot, open abdomen, sternal infections etc.
- 9. Should have capacity to engage 4 Canister at a time disposable canister with bacteria filter & waste solidifier and should have minimum of 500ml capacity and canister is available and can be used with 1000 ml
- 10. The system should have digital & touch display screen with screen lock facility for unauthorized handling and should be able to operate on Fingers and Stylus.
- 11. Should have sophisticated alarms for safety and troubleshoot, should be portable & light weight not more than 7.3 kg.
- 12. It should have microprocessor-controlled pressure (-50-200mmHg) settings with steps of 25mmHg to efficiently treat entire range of wound etiologies & sizes
- 13. It should be electrically operated and have at least 6-8 hours internal battery backup for enhanced patient freedom
- 14. It should have double layer filter system capable for reducing bacteria, infection & wound odor
- 15. It should have microprocessor-controlled system for enhanced accuracy, maintain target negative pressure even during patient movement
- 16. It should be able to monitor, and It should have the capability to alert the user of tubing blockage, pressure leakage, canister full, therapy inactive or any malfunctioning to maximize patient safety
- 17. System should have fixed tubing to obtain controlled & infection free dressing.
- 18. The system should operate under 100V to 240V (50/60Hz) Power supply
- 19. The System should have night mode facility to minimize the disturbance to the patient because when the night mode is active then ON-OFF Switch light will be dim and screen will be black.
- 20. USB and Memory Card Ports for downloading Patient data and Wound Size analysis.

21. The Systems should have an USFDA and CE Certifications

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#### Warranty and penalty

- 1. It will carry a comprehensive warranty for 5 years (including all spares, accessories, consumables if any) and provision for CMC for next 5 years.
- 2. The firm should indicate in the technical bid itself that the prices of all standard accessories as well as the other items & accessories specifically mentioned in the specifications are included in the quoted price.
- 3. The firm will give rate list of all possible spares, accessories & consumables if any, as part of financial bid. If price of any spare is not mentioned and is required for the Operation or repair in life time of equipment/instrument, then the firm will be obliged to give it free throughout the life cycle of the equipment.

#### Consumables of Multi Use Wound Healing Device

- 1. Medium Grey GRANUFOAM™ Silver(Micro-bonded metallic silver is uniformly distributed throughout the dressing, providing silver even after sizing) Dressing (18 x 12.5 x 3.2cm), 2 sheets of V.A.C.® Drape, 1. five lumen of SENSAT.R.A.C.™Pad with connector, 1 disposable ruler
- 2. Large Grey GRANUFOAM™ Silver (Micro-bonded metallic silver is uniformly distributed throughout the dressing, providing silver even after sizing) Dressing (26 x 15 x 3.2cm), 2 sheets of V.A.C.® Drape,1. five lumen of SENSAT.R.A.C.™Pad with connector, 1 disposable ruler
- 3. Small Grey GRANUFOAM<sup>TM</sup> Silver (Micro-bonded metallic silver is uniformly distributed throughout the dressing, providing silver even after sizing) Dressing (10 x 7.5 x 3.2cm), 1 sheet of V.A.C.® Drape, 1 SENSAT.R.A.C.<sup>TM</sup> Pad, five lumen of SENSAT.R.A.C.<sup>TM</sup>Pad with connector, 1 disposable ruler
- 4. Canister (Sodium polyacrylate Gel) 1000 ml with Five lumen track pad for Rx4 units.
- 5. Please find enclose following documents along with the quotes/Offer.
  - a. Registration certificate under the Drugs and Cosmetic Act India
  - b. Import License copy India
  - c. US FDA Certificate
  - d. CE Certificate
  - e. ISO Certificate

Declaration: The specification for the item above are general, broad based, space, personnel are available for the equipments and it is not specific to favour any particular item or any particular firm.

Medical Supering A.I.I.M.S. Hospital New Delhi-110020

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### All India Institute of Medical Sciences Ansari Nagar, New Delhi-110029

# rietary/ Specific Brand /Goods Certificate

1. Item/Type/Model No. required: along with specification

Wound Management Device Model: V.A.C RX4

2. Is the Item a spare part attachment or accessory for an existing equipment. No

3. Name of manufacturers/supplier of the: item proposed by the indenter.

Principle: M/s KCI USA, Inc. Local Agent: M/s Nanak Enterprises

Unit/Shop: 110, First floor, CSC, Shakti apartment Shubham Enclave, Paschim Vihar, New Delhi-63

4. Are they sole manufacturers/Sole: distributor of the item.

Yes

5. Is there any item with similar/ equivalent: Specification available in the market to meet the job requirement envisaged. If the answer is yes, why the same can't be procured, demanding officer should bring out comparative functional advantages/Cost effectiveness of the recommended item from these offers by other.

No

6. What were the efforts made to locate alternative:

- Through Internet & No Other alternative source for supply of other substitutes
- 7. Why open/limited tender can't be resorted to,: for locating alternative source.
- These are proprietary items of M/s KCI USA, Inc.
- 8. Are the proprietary items certifying that the: rates are reasonable or not.
- Yes, Rates certificate from the firm is Enclosed

9. Any other justification for procuring items: from single source

Signature of Indenter

(Demanding nafficeP). LARHIRAM MURAN

(Dr. Meera GUIO)

STATE /Professor Countersigned

is definitely known that brand proposed was advantage in meeting our functional requirements and limited tender system could be dispensed with as they would serve no useful purpose in this particular case.

(Strike out whichever is not applicable)

( Par Property)



## To whom so ever it may concern

We hereby confirm that if our Local Authorized supplier for AIIMS Delhi is not able to provide the Service under CAMC & Warranty condition than the principle company is responsible for CAMC & Warranty for the entire contract period under same terms & conditions.

#### Yours Sincerely

THANKING YOU
FOR KCI MEDICAL INDIA PVT LTD



Rajkumar Mandal Regional Sales manager (Govt Account) rmandal@mmm.com Mob-9958087666

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# To whom so ever it may concern

This is to certify that KCI USA Inc. ("KCI") is the legal manufacturer of the VAC RX4 Therapy Unit (Collectively the "Proprietary Articles"). as quoted by us in our quotation is a Proprietary Product manufactured by KCI USA Inc located at 12930 Interstate 10 west San Antonio, TX 78249 USA.

We are the sole supplier of the Product. It is not manufactured by any other firms as the best of our knowledge.

Yours Sincerely

THANKING YOU FOR KC! MEDICAL INDIA PVT LTD



Rajkumar Mandai Regional Sales manager (Govt Account) <u>rmandal@mmm.com</u> Mob-9958087666 কা, ভারীনার ভূরী/Dr. 1000MPA, 4 00000 আন্তর্গ/পার্চাব্যর্কার ভূমান বিশ্বরাধী বিশ্বরাধী বিশ্বরাধী বিশ্বরাধী ভূমান বিশ্বরাধী ব





# **Proprietary Article Certificate**

June 29, 2020

To Whom It May Concern:

This is to certify that KCI USA Inc. ("KCI") is the legal manufacturer of the V.A.C.RX4™ Therapy Unit (collectively, the "Proprietary Articles"). KCI further certifies that its affiliate KCI Medical India Private Limited ("KCI India") is its authorized distributor for the Proprietary Articles in India.

Yours sincerely,

Terrie McDaniel

Regulatory Affairs Manager

KCI USA Inc.

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# SECTION – X MANUFACTURER'S AUTHORISATION FORM

The 'Director.

All India Institute of Medical Sciences

Ansari Nagar, New Delhi-110029, India.

Dear Sir, Ref: Authority Letter

We, KCI medical India Pvt Ltd. who are proven and reputable manufacturers Of Acti Vac Device (Wound healing device) hereby authorize Messrs. Nanak Enterprises Office at OfC/Unit No:-110, first floor ,CSC, Shakti Apartment, Shubham Enclave, Paschim Vibar, New Delhi -110063 to submit a bid, process the same further and enter into a contract with you against your requirement as contained in the above referred TE documents for the above goods manufactured by us.

We also state that we are not participating directly in this bid for the following reason(s): As manufacturer it is not possible to participate in all tenders worldwide, therefor we use the services of Distributors.

We further confirm that no supplier or firm or individual other than Messrs. Nanak Enterprises Office at OfC /Unit No:-110, first floor ,CSC, Shakti Apartment, Shubham Enclave, Paschim Vihar, New Delhi--110063 is authorized to submit a bid, process the same further and enter into a contract with you against your Requirement as contained in the above referred TE documents for the above goods Manufactured by us.

We also hereby extend our full warranty, CAMC as applicable as per clause 15 of the General Conditions of Contract, read with modification, if any, in the Special Conditions of Contract for the goods and services offered for supply by the above firm against this TE document.

We also hereby confirm that we would be responsible for the satisfactory execution of contract placed on the authorized agent and the spares for the equipment shall be available for at least 10 years from the date of supply of equipment.

We also confirm that the price quoted by our agent shall not exceed the price which we would have quoted directly"

We also confirm that in case we change appointed Indian agent during Comprehensive warranty/CAMC period, all accepted liabilities will be fulfilled/accepted by me (OEM) or our new appointed Indian agent without any additional cost and conditions.

Assuring best services always. Thanking you

FOR KCI MEDICAL INDIA PVT LTD

Rajkumar Mandal Regional Sales manager (Govt Account) Imandal g mmm com Mob-9958087666 ( Deeme



# ALL INDIA INSTITUTE OF MEDICAL SCIENCES ANSARI NAGAR, NEW DELHI - 110029

#### Proprietary Article Certificate (PAC) (Machinery & Equipment)

- (i) The indented goods are manufacture by M/s KCI USA, Inc.
- (ii) Item Name: Wound Management Therapy Device
- (iii) Model No: V,A.C RX4
- (iv) Vital Technical Performance Parameters required which makes the requirement proprietary##

This is a new instrument having 4 separate channels in a single device with separate individual settings -individual pressure, intensity and mode can be assigned at the same time. This system have 04 digital & touch display screen with screen lock facility for unauthorized handling and should be able to operate on Fingers and Stylus. It provides unique and innovative technique of wound healing with double layer filter system capable for reducing bacteria, infection & wound odor. It is particularly helpful in wound in areas like face, hand& foot, which can after be difficult to reach and contour with conventional modalities.

(v) No other make or model is acceptable for the following reasons

Due to unique and innovative technique of wound healing no other make or model is acceptable

it is certified that market survey has been done and found that no other manufacturer is manufacturing similar/equivalent specifications which can fulfill the vital requirements of end user.

Signature of TSEC

With Name, Designation, Department อดิเมล เมื่อกรุงเฟเลส์เด่นอดบ

डॉ. भीर। एवका, एमडी/Dr. Meera Ekka, MD सहावक आचार्य/Assistant Professor आपतकालीन विकित्सा विभाग/Deptl. of Emergency Medicine स्वभावज्ञावसंव, अंसारी नगर/A.U.M.S., Anseri Nagar आपार्य/Professor आपातकातीन विक्तिस विधान/Deptt. of Emergency Medicine अक्षाव्याकराव, असारी नगर/A.I.I.M.S., Ansari Nagar नई विस्ती-110029/New Delhi-410029

##Note: TSEC should clearly mention the vital functional parameters requirements with the processor of the p

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Dr. PRAKASH RANJAN MISHRA सहायक आचार्य/Assistant Professor

आपातकातीन चिकित्सा विभाग/Dept. of Emergency Medicine अ.भा.आ.सं.. मई दिल्ली-29/A.I.I.M.S., New Delhi-29