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

Ref. No. 19/Stores(DO)/G.M./PAC/2019-20/FSC Dated-17/10/2019

Sub:- Purchase of "Urinary Incontinence Device – 01 No." for the Department of Geriatric Medicine at AIIMS, New Delhi-110029, on proprietary basis Inviting comments thereon.

The Institute is in the process to purchase "Urinary Incontinence Device – 01 No. at AIIMS, New Delhi from M/s. BTL Emsella, United Kingdom through M/s. BTL India Pvt. Ltd., New Delhi. The PAC Certifications by M/s. Emsella, United Kingdom 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. 19/Stores(DO)/Pead.Surg/PAC/2019-20/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 08/11/2019 upto 12.30 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.

Department of Geriatric Medicine AIIMS, New Delhi

Technical specification of Urinary Incontinence Device

No. of Equipment - One

Approx Cost - 62 Lacs

- 1. It Should have Pre-programmed protocols
- 2. The therapy system must consist of Basic Device with control programs & Therapy Chair
- 3. The device should allow supramaximal pelvic floor muscle contractions.
- Large Touch Color screen display of control unit 5 inches or more
- 5. The Electromagnetic field intensity should be from 0.7 to 2.5 Tesla
- 6. Frequency range from 1.0 Hz to 150.0 Hz
- 7. The Chair should be having cool flow technology for unlimited work outs (no heating at the surface)
- 8. Patients should be able to take the treatment fully clothed (no need to take out cloths)
- 9. Class according to MDD 93/42/EEC II a
- 10. The unit should have US FDA certification
- 11. It should have minimum warranty of five years and further CMC for Five years.

Dr. Vijay Kumar Assistant Professor

Department of Geriatric Medicine A.I.I.M.S., New Delhi-110029

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All India Institute of Medical Sciences Department of Geriatric Medicine

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Proprietary Article Certificate (PAC) (Machinery & Equipment)

- (i) The indented goods are manufactured by M/s BTL Industries Ltd. (United Kingdom)
- (ii) Item Name:- BTL EMSELLA
- (iii) Model No:- BTL EMSELLA
- (iv) Vital Technical Performance Parameters required which makes the requirement proprietary:- High Intensity Focussed Electromagnetic field technology
- (v) No other make or model is acceptable for the following reasons:- As no other make make model is avoidable with fligh Intensely focused. Electromagnetic field fectivo-logy. 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 and Hospital/Institute/DGHS

Dr. Avinash Chakrawarty

Dr. Avinash Professor

Assistant Professor

Deptt. of Ceriatric Medicine

Deptt. of Ceriatric New Delhi-110029

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Date: 04.07.2019

To Whomsoever It May Concern

Proprietary Article Certificates

We M/s BTL India Pvt. Ltd. a fully owned subsidiary of M/s BTL Industries Ltd. 161, Cleveland Way, SG1 GBU Hertfordshire, United Kingdom hereby confirm that our following products are proprietary products of:

BTL Industries Ltd. 161, Cleveland Way, SG1 GBU Hertfordshire, **United Kingdom**

BTL-Emsella

Patented HIFEM device (High Intensity Focussed Electromagnetic technology)

Features:

- 1. US FDA approved and it is registered with US Patents and Trademark office;
- U.S. Patent Application No. 14/873,110 filed October 1, 2015; now U.S. Patent No. 9,586,057,
- U.S. Patent Application No. 14/789,658 filed July 1, 2015; now U.S. Patent No. 9,636,519, issued
- U.S. Patent Application No. 15/073,318 filed March 17, 2016; now U.S. Patent No. 9,919,161,
- 2. Therapy systems has Basic device with control program and Therapy Chair having cool flow technology for unlimited work outs (no heating at the surface); and having penetration depth of at least 10 cms or more using Intensity of up to 2.5 Tesla.
- 3. The Pulse frequency repetition rate is 1 to 150 Hz for supra maximal Pelvic floor muscle contraction and relaxation; which is clinically proven to manage all stages and types of Urinary
- 4. Patients remain fully clothed and the device is operator free.

We also confirm that the above-mentioned proprietary products are manufactured by us and have a patented technology.

Yours faithfully

BTL Industries Limited 161 Cleveland Way

Stevenage SG1 6BU Hertfordshire United Kingdom

Name: Marius Iordan

Designation: International Manager

For and on behalf of M/s BTL Industries Ltd.

Assistant Professor Assistant Professor Department of Geriatric Medicine A.I.I.M.S., New Delhi-110029

Deptt. of Geriatric Medicine 29

Deptt. of Geriatric Medicine 311.0029 Department of Geriatric Medicine

Dr. A.B. Dey Professor & Head Linespoi a Liean Wedicine AIIMS, New Delhi-110029

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MANUFACTURER'S AUTHORISATION

To, The 'Director' All India Institute of Medical Sciences Ansari Nagar, New Delhi-110029, India.

Date: 04 Oct., 2019

Dear Sir,

We M/s BTL Industries Ltd. who are proven and reputable manufacturers of Physiotherapy & Aesthetic devices/ equipment's (BTL EMSELLA, Patented HIFEM device - High Intensity Focused Electromagnetic Technology) having factories at 161, Cleveland Way, SGI GBU Hertfordshire, United Kingdom hereby authorize our India office to quote on our behalf for our range of products against the above-mentioned tender:

Messrs BTL India Pvt Ltd 180-E. Lane W6B, Sainik Farms, Saket New Delhi-110062

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 further confirm that no supplier or firm or individual other than Messrs BTL India Pvt Ltd, 180-E, Lane W-6B, Sainik Farms, New Delhi-110062 is authorised 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/ authorized channel partner shall not exceed the price which we would have quoted directly"

Yours faithfully, For BTL Industries Ltd.

Marius Iordan International Manager

Industries Limited Cleveland Way SG1 6BU Hermordshir Stevenage United Kingdom

Monent of Geriatric Medicine AIIMS, New Delhi-110029

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Assistant Professo,

1002 Department of Geriatric Medicine Assistant Professor A.I.I.M.S., New Delhi-110029