

All India Institute of Medical Sciences, Jodhpur

No. Admn/Prop/79/2021-AIIMS.JDH

Dated: 27th December, 2021

Subject: Proposal for Purchase of Biopsy Forceps, EUS-FNB Needle, TTS Structure Dialatation Balloon and Hemoclips, Make: Boston Scientific for the Dept. of Gastroenterology on Proprietary basis at AIIMS Jodhpur – Inviting Comments/Objection thereon.

The Institute is in the process of purchasing Biopsy Forceps, EUS-FNB Needle, TTS Structure Dialatation Balloon and Hemoclips, Make: Boston Scientific for the Dept. of Gastroenterology at AIIMS, Jodhpur from M/s Boston Scientific India Pvt. Ltd., Gurgaon through its authorized dealer M/s Renix, Jodhpur. The proprietary certificate submitted is attached & uploaded on website.

The above documents are being uploaded for open information to submit objection, comments, if any, from any manufacturer regarding proprietary nature of the above said Biopsy Forceps, EUS-FNB Needle, TTS Structure Dialatation Balloon and Hemoclips, Make: Boston Scientific for the Dept. of Gastroenterology within 7 days from the date of issue/uploading of the notification. The comments should be sent to Deputy Director, AIIMS Jodhpur on or before 03rd January, 2022 up to 03:00 PM, failing which it will be presumed that any other vendor is having no comment to offer and case will be decided on merits.

Deputy Director (Admin.)

Enclosure: Related documents enclosed

Details of Items to procured:

S. No.	Item Name	Specifications
1	Biopsy Forceps	 Unique distal assembly designed – Designed to acquire up to 4 tissue samples in a single pass Micro – Mesh teeth – facilitate a clean-cut tissue with minimal tearing and crushed artifact Endoglide coated sheath Colour Coding for upper GI Endoscopy and colonoscopy Country of Origin Certificate from OEM Should be European EC (4 digit notified body number) or US FDA certified or Bureau of Standard of India approved
2	EUS-FNB Needle	 The Franseen Needle tip design 22Ga Needle Three Symmetrical Cutting Surface with fully Formed Heels Cobalt Chromium Material Echogenic Pattern Extends to the Needle Tip Custom sheath Sizes Control Zone and Lubricomp Polymer Country of Origin Certificate from OEM Should be European EC (4 digit notified body number) or US FDA certified or Bureau of Standard of India approved
3	Through The Scope (TTS) stricture dilatation balloon	 Multi Diameter Balloon – Three distinct sizes at three distinct pressure. Balloon made up of PEBEX – A non-compliant material. Rounded shoulders of balloon for endoscopic visualization and evaluation during procedure. Separate length of deliver system for upper GI endoscopy and colonoscopic usage Sizes: 8-10 mm, 10-12 mm, 12-15 mm, 15-18 mm. Country of Origin Certificate from OEM Should be European EC (4 digit notified body number) or US FDA certified or Bureau of Standard of India approved
4	Hemoclips	 Re-Opening capabilities up to 5 times Pre-Loaded clips- Ready to use 360 rotation, 1:1 rotation 11 mm wide jaw span- intended to grasp a sizable amount of tissue 32 wire braided catheter Available in 155 & 235 cm Length Country of Origin Certificate from OEM Should be European EC (4 digit notified body number) or US FDA certified or Bureau of Standard of India approved

Boston Scientific Corporation 300 Boston Scientific Way Mariborough, MA 01752 USA

23-Jul-2021

To Whomsoever It May Concern:

This is to certify and confirm that Boston Scientific Corporation is the sole manufacturer of the products "Multibite Single Use Biopsy Forceps" and it is a proprietary product of Boston Scientific Corporation.

Yours Sincerely,

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Katy Peterson Director-Corporate Regulatory Affairs Global Operations Boston Scientific Corporation



Scientific

Boston Scientific Corporation 300 Boston Scientific Way Mariborough, MA 01752 USA

13-Jul-2021

To Whomsoever It May Concern:

This is to certify and confirm that Boston Scientific Corporation is the sole manufacturer of the product "Acquire Endoscopic Ultrasound Fine Needle Biopsy (FNB) device" and it is a proprietary product of Boston Scientific Corporation.

Yours Sincerely,

aty Peter

Katy Peterson Director-Corporate Regulatory Affairs Global Operations Boston Scientific Corporation

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Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA 01752 USA

13-Jul-2021

To Whomsoever It May Concern:

This is to certify and confirm that Boston Scientific Corporation is the sole manufacturer of the product "CRE Wireguided Balloon Dilatation Catheter" and it is a proprietary product of Boston Scientific Corporation.

Yours Sincerely,

Katy Peter

Katy Peterson Director-Corporate Regulatory Affairs Global Operations Boston Scientific Corporation



Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA 01752 USA

13-Jul-2021

To Whomsoever It May Concern:

This is to certify and confirm that Boston Scientific Corporation is the sole manufacturer of the product "Resolution 360 clip" and it is a proprietary product of Boston Scientific Corporation.

Yours Sincerely,

Katy Peter

Katy Peterson Director-Corporate Regulatory Affairs Global Operations Boston Scientific Corporation



BSC Ref. No.: BSCI/AIIMSJODHPUR/ENDO/14072021/4357

To, The Director, All India Institute of Medical Sciences(AIIM5) Jodhpur, Industrial Area, Basni, Phase – Ilnd, Jodhpur (Raj.) July 14, 2021

Sub: Dealer Authorization Letter for Supply in AllMS Jodhpur

This is to confirm that till further notice, M/s RENIX is authorized to receive orders, supply products, raise bills, collect payment and replace any defective item for Boston Scientific's -Endoscopy range of products.

The contact detail of M/s RENIX is as follow

Plot No J-177, Gall No-4/3, Opp. Ricco Park Basini IInd Phase Jodhpur Rajasthan- 342006.

Mr. Raghu Raj Agarwal, Proprietor 0291-2743245, 9414143245 recriss0808@gmail.com

The Desler Agreement and its agreed renewal/extension with M/s RENIX shall expire in due course on 31st December 2021. In case the said dealer agreement is not renewed post 31st December 2023, Boston Scientific shall maintain un-interrupted supply of its products to your hospital through its other authorized dealers and inform in writing about the same. We also wish to confirm the following:

- If authorized dealers and inform in writing about the same. We also wish to confirm the following: The specific technical, clinical, service or financial terms and conditions under this tender shall be complied to the extent possible on the nature of products being quoted. The Markings and labelling on the Products shall be in full compliance of terms of Drugs and cosmetic act 1940, Medical Device Rules 2017, and Legal Metrology (Packaged Commodities) Rules, 2011 as amended by (Amendment) Rules, 2017 amended till date for the purpose of import and sale into India. The Shall life of the Products shall be in full compliance of terms of Drugs and cosmetic act 1940 & Medical Device Rules 2017, amended till date for the purpose of import and sale into India. . .
- .
- The Shelf are of the Products shall be in on comparate of learning of learning and regulators and regulatory bodies like NPPA, such that these for the purpose of import and sale into India. We hereby confirm that prices quoted / approved may be governed by certain regulations and regulatory bodies like NPPA, such that these quoted / approved prices are subject to change as per government directives. Any such change that such regulatory or statutory bodies like NPPA prescribe, will have to be mandatorily accepted by the Supplier and the Institution purchasing the products under the Tender/ Rate contract. .
- prescribe, will have to be mandatonly accepted by the supplier and the institution purchasing the products under the Tender/ Kate contract. We hereby confirm that as per currently available information, the products which we are being quoted in this tender are not getting phased out, however Discontinuation is a possibility in unavoidable discurstances in which cases a parallel version or a higher-grade version will be provided for a limited number on the RC approved prices. However, if there is a variation in the prices, it will be mutually discussed at that stage Price submissions made under this tender / RC are independent. Any compliance requirement to fall clause or such restrictions is subject to Nanual for procurement of Goods by Ministry of Finance as adopted by department of Pharmaceuticals. .

M/s RENIX is required to pursue and conduct all activities with respect to this authorization by Boston Scientific India, in full compliance of all laws, Code Boston Scientific regulations and

regulations and Boston Scientific https://www.bostonscientific.com/content/dam/bostonicientific/comporate/chirenship/compliance-https://www.bostonscientific.com/content/dam/bostonicientific/comporate/chirenship/compliance-ethics/Code%2005%20Conduct/citizenship code of conduct english 001000 Rev AN.pdf. This is for your information and records.

5 Best regards

Gurgaon Pol.

Vibhav Garg Director – India HUE & ASEAN Boston Scientific India Pvt. Ltd.



Registered Office: C-40/41, Okhis industrial Area, Phase II, New Delhi 116 020 INDIA Tel.: +91-11-4161 1024 Fax : +91-11-4151 1023 CIN No.:U33119DI2005FTC121242

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