

**DEPARTMENT OF GASTROENTEROLOGY  
ALL INDIA INSTITUTE OF MEDICAL SCIENCES**

Reference:23/Gastro./Proprietary/Spyscope      Digital      Access      &      Delivery  
Cath/Endo.Accessory/2017-18

October 30, 2017


**Subject:** Purchase of Spyscope Digital Access & Delivery Cath for endoscopy room, Department of Gastro., AIIMS, New Delhi, on proprietary basis- Inviting comments thereon.


The Department of Gastroenterology has been procuring the above cited endoscopy accessory (Digital Access & Delivery Cath - 05 Nos), with mentioned volumes from M/s Bio Services, on proprietary basis. The proposal submitted by M/s Boston Scientific and PAC certifications are attached & uploaded on website.

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 days from the date of issue/uploading of the notification giving reference no.23/Gastro./Proprietary/Spyscope Digital Access & Delivery Cath/Endo.Accessory/2017-18

The comments should be sent to Professor & Head, Department of Gastroenterology, Room No. 3111, Teaching Block, 3<sup>rd</sup> Floor, AIIMS, New Delhi on or before 14 November 2017 upto 5:00 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 sincerely,

  
Dr. Anoop Saraya  
Prof. & Head

  
Dr. Pramod K. Garg  
Professor  
(Demanding Officer)

**Encl:**

DL No. 9 (2580) 20B & 21B  
TIN: 07590162574  
PAN: AADFB8378H

Phone : 252.  
25278



# BIO SERVICES

ISO 9001:2008

Dealers in:- DIAGNOSTICS, CHEMICALS & SURGICALS

A-1/7, PASCHIM VIHAR, NEW DELHI-110063

Quot Ref: BioSer/SEPT/1084

26.09.2017

To,

The H.O.D.  
Dept Of Gastroenterology  
AIIMS, Ansari Nagar,  
New Delhi.

Dear Sir,

Sub- Quotation for Boston Scientific Intl Endoscopy Division

We are pleased to quote the rate of Boston Scientific as follows:-

<u>ITEM NAME</u>	<u>CAT NO</u>	<u>QTY</u>	<u>UNIT PRICE</u> ( in Rs.)	<u>MRP</u> ( in Rs.)
SPYSCOPE DIGITAL ACCESS & DELIVERY CATH	4660	01	1, 77,240.00	2, 60,000.00

GST @ 12 % will be charged extra.

Thanking You

Yours Faithfully  
For Bio Services

Manager

DL No. 9 (2580) 20B & 21B  
TIN: 07590162574  
PAN: AADFB8378H

Phone : 25278664  
25278665



# BIO SERVICES

ISO 9001:2008

Dealers in:- **DIAGNOSTICS, CHEMICALS & SURGICALS**

A-1/7, PASCHIM VIHAR, NEW DELHI-110063

## PROPRIETARY AND RATE RESONABLE CERTIFICATE

THIS IS TO CERTIFY THAT THE RATES QUOTED BY US IN OUR PERFORMA INVOICE NO **BioSer/SEPT/1084 DATED 26.09.2017** IS NOT HIGHER THAN THOSE, WHICH ARE CHARGED FROM OTHER GOVT. /SEMI GOVT. DEPT. IN INDIA.

IT IS ALSO CERTIFIED THAT SALES TAX CHARGES IN THE BILLS ARE CORRECT AND AS PER SALES TAX RULE.

THIS CERTIFICATED IS ALSO VALID FOR OUR BILLS OF SALE/INVOICES GENERATED SUBSEQUENTLY AT THE TIME OF SUPPLYING MATERIAL FOR YOUR ORDERS ON THE ABOVE PERFORMA INVOICE.

WE DO ALSO CERTIFY THAT PRODUCTS QUOTED (QUOTATION No- BioSer/SEPT/1084 DATED 26.09.2017) BY US ARE PROPRIETARY ITEMS OF OUR PRINCIPAL BOSTON SCIENTIFIC INDIA PVT LTD.

FOR BIO SERVICES

Ref. No.: BSCI/ENDO/AIIMS/26052017/1361

To,  
The Director,  
AIIMS,  
New Delhi  
May 26, 2017

**Sub: Dealer Authorization letter to quote under PAC**

Dear Sir,

This is to confirm that M/s BIO SERVICES is authorized to quote, receive order, supply products, raise bills, collect payment and replace any defective item for Boston Scientific's – Endoscopy range of products quoted under PAC.

The contact details of M/s BIO SERVICES is as follows:

M/s BIO SERVICES  
63, LSC, A1 Block  
Pashim Vihar  
New Delhi 110063

Contact Person: Mr. Suresh Kapoor  
Contact Number: 011-25278664, 9810026601

The dealer agreement with M/s BIO SERVICES shall expire in due course on 31st December 2017. In case the said dealer agreement is not renewed post 31st December 2017, 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.

This is for your information and records.

Best regards

  
**Rahul Garg**  
Business Unit Director

Boston Scientific India Pvt. Ltd.



(17)

**Central Drugs Standard Control Organisation**  
**Directorate General of Health Services**  
**Ministry of Health & Family Welfare**

Food and Drug Administration Bhawan  
Kotla Road, New Delhi-110002

File No.: 31-1634-MD/2014-DC (End. 01)

Dated

To,

✓ M/s. Boston Scientific India Pvt. Ltd.,  
C-41 Ground Floor, Okhla Industrial Area,  
Phase-II, New Delhi-20.

29 SEP 2015

SUB: -Endorsement No. 01 to R.C. No. MD-1634 of manufacturing site M/s. Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA 01752, USA having manufacturing premises at M/s. Boston Scientific Corporation, 780 Brookside Drive, Spencer, IN 47460 USA under the provisions of Drugs & Cosmetics Rules for the purpose of import of medical devices in India

Sir,

Please refer to your application no. BSC/F41/2015/04 dated 21.04.2015 received by this office vide diary No. 12752 dated 21.04.2015 on the subject cited above.

Registration Certificate in Form 41 under the Drugs and Cosmetics Rules is herewith for the manufacturing site alongwith the name(s) of medical device(s) imported under the said Certificate subject to the following conditions.

1. The medical device(s) shall conform to the standards / specifications mentioned in the Second Schedule of the Drugs and Cosmetics Act/ ISO / MDD / or such other standards or specifications approved by this Directorate.
2. Dispute, if any, in respect of the payment of fees and submission of TR6 challan, shall be settled between the bank and the applicant.
3. The medical device will be required to be withdrawn from sale from the market in case any undesirable reactions due to failure of the device or its accessories are brought to light at any stage. This Directorate should be informed of adverse reports on the medical device, if any.
4. This registration in no way relieves you of the responsibility of complying with other provisions of the Drugs & Cosmetics Act and Rules thereunder, and any other provisions of any other Act and Rules applicable in the matter concerned.
5. Each consignment of the medical device(s) to be imported by you shall be accompanied by a test / analysis reports.
6. Based on this registration, applications for the import of medical device(s) endorsed in the enclosed Registration Certificate shall be considered for the issue of Form 10




7. This Registration Certificate is being issued under the condition that during the pendency of Registration, the applicant may be required to deposit inspection fee as stipulated under Clause (5) of Rule 24-A and enable inspection of manufacturing site by the officials Authorized for this purpose. Non-compliance to this condition as and when so directed would result in cancellation of Registration Certification.

Please note that Registration Certificate issued is liable to be suspended / cancelled, if any of the condition stipulated above is not complied with, apart from any other condition that may be taken under the provisions of the Drugs & Cosmetics Act, 1940 and the Rules thereunder.

Please acknowledge the receipt.

Yours faithfully,



  
(Dr. S. Eswara Reddy)  
Joint Drugs Controller (I)



Government of India  
Central Drugs Standard Control Organisation  
Ministry of Health & Family Welfare  
FDA BHAWAN, KOTLA ROAD, New Delhi – 110 002 (India)

NAME OF MEDICAL DEVICES WHICH MAY BE IMPORTED ON ENDORSEMENT  
NO. 01 UNDERREGISTRATION CERTIFICATE NO. MD-1634 VALID UPTO  
15-08-2018

ENDORSEMENT NO. 01  
NAME OF PRODUCT(S)

S. No	Category	Device Details
1.	Catheter	<p>A. Generic Name : Catheter</p> <p>B. Brand Name : SpyScope DS Access and Delivery Catheter</p> <p>C. Model Name: M00546600</p> <p>D. Components : (1) SpyScope DS Access and Delivery Catheter (2) Y-Port Adapter</p> <p>E. Intended Use: The SpyScope DS Catheter is intended to provide direct visualization and to guide both optical and accessory devices for diagnostic and therapeutic applications during endoscopic procedures in the pancreatobiliary system including the hepatic ducts.</p> <p>F. Shelf Life : 1 year</p>

(ITEM(S) ONE ONLY)

Place: New Delhi  
Date:

Licensing Authority  
Seal/Stamp

29 SEP 2017

डॉ. रा. ईश्वरा रेड्डी / Dr. S. ESWARA REDDY  
सामान्य औषधि नियंत्रक (भारत) / Jt. Drugs Controller (India)  
केन्द्रीय औषधि कन्ट्रोल ऑरगनाइजेशन फॉर इण्डिया  
CDSCO (DIO) One, Patparganj, New Delhi - 110092  
फ़ोन: 26101111, 26101112, 26101113, 26101114, 26101115, 26101116, 26101117, 26101118, 26101119, 26101120, 26101121, 26101122, 26101123, 26101124, 26101125, 26101126, 26101127, 26101128, 26101129, 26101130, 26101131, 26101132, 26101133, 26101134, 26101135, 26101136, 26101137, 26101138, 26101139, 26101140, 26101141, 26101142, 26101143, 26101144, 26101145, 26101146, 26101147, 26101148, 26101149, 26101150, 26101151, 26101152, 26101153, 26101154, 26101155, 26101156, 26101157, 26101158, 26101159, 26101160, 26101161, 26101162, 26101163, 26101164, 26101165, 26101166, 26101167, 26101168, 26101169, 26101170, 26101171, 26101172, 26101173, 26101174, 26101175, 26101176, 26101177, 26101178, 26101179, 26101180, 26101181, 26101182, 26101183, 26101184, 26101185, 26101186, 26101187, 26101188, 26101189, 26101190, 26101191, 26101192, 26101193, 26101194, 26101195, 26101196, 26101197, 26101198, 26101199, 26101200, 26101201, 26101202, 26101203, 26101204, 26101205, 26101206, 26101207, 26101208, 26101209, 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26102210, 26102211, 26102212, 26102213, 26102214, 26102215, 26102216, 26102217, 26102218, 26102219, 26102220, 26102221, 26102222, 26102223, 26102224, 26102225, 26102226, 26102227, 26102228, 26102229, 26102230, 26102231, 26102232, 26102233, 26102234, 26102235, 26102236, 26102237, 26102238, 26102239, 26102240, 26102241, 26102242, 26102243, 26102244, 26102245, 26102246, 26102247, 26102248, 26102249, 26102250, 26102251, 26102252, 26102253, 26102254, 26102255, 26102256, 26102257, 26102258, 26102259, 26102260, 26102261, 26102262, 26102263, 26102264, 26102265, 26102266, 26102267, 26102268, 26102269, 26102270, 26