



**NEIGRIHMS**  
**North Eastern Indira Gandhi Regional Institute of Health & Medical Sciences**  
(An Autonomous Institute, Ministry of Health and Family Welfare, Government of India)  
Directors Block Mawdiangdiang, Shillong, Meghalaya-793018

F.No:NEIGR/S&P/TB - 01/2022-23

Notification of Award No:NEIGR/S&P/OT/G-226/23-24/GEMC-511687792767330

PO ID:PO06230001 / Approved Date:15-06-2023

Date 15-06-2023

Indent-No: IN06230001

To

M/s SPSS Mediline,  
M/s SPSS Mediline, 88, Flyover Market, Defence  
Colony, New Delhi - 110024, Tel:9999969798,  
spssmediline@gmail.com

**Principal:**

M/s FUJIFILM India Private Limited,  
Unitech Cyber Park, Unit No.801-807, 8th  
Floor, Tower C, Sector 39, Gurugram,  
Haryana - 122001, Tel:91-124-4325500,  
contact@fujifilm.com

Sub: Award for Supply Installation Testing and Commissioning of one unit of Slim Diameter Video Bronchoscope with 2.0 mm working channel with 5 years warranty and thereafter 5 year CMC for department / section of Tuberculosis and Respiratory Diseases.

Reference:

- Tender Enquiry No: GEM/2023/B/3162547
- Offer No: NA
- Price Justification No:12074-75/F/MC/Store/PG Seats/2022-23. Dated - 2-3-2023
- Price Discount Letter No:NA
- PO Remarks:Approved in the Meeting of the 65th Procurement Committee for NEIGRIHMS, Shillong held on 21/03/2023, Vide agenda no - C -17/65, The time schedule for Supply, Delivery, Installation. Testing and Commissioning should be completed within 3rd of July 2023

This Order/Memorandum issues with concurrence of Finance Branch vide their UO No C - 16/2023 - 24 Dated 17-04-2023

Dear Sir/Madam,

With reference to Tender Enquiry No: **GEM/2023/B/3162547** and your Bid/Offer **NA** in response an order is hereby placed on you for the complete turnkey contract of supply, transportation, installation, commissioning, provision of technical assistance, after sales service, maintenance service and other such obligations of the tenderer, training at bidders cost and demonstration of Medical equipment at this Institute, as per details indicated herein.

This order which is intended for the supply of the store detailed in the scheduled below, in accordance with the terms & conditions of NEIGRIHMS /Government of India and in the manner specified herein, shall operate to create a specific contract between the contractor (with whom the contract referred to and the requisition are placed) on one part and NEIGRIHMS, Shillong, on the other part.

| Sl. No | Description Of Goods   | Unit | Rate Per Unit | Total Amount on(DDP at Consignee Site) |
|--------|--|------|---------------|--|
| 1      | <b>Slim Diameter Video Bronchoscope with 2.0 mm working channel</b><br><b>(Make:FUJIFILM India Private Limited,Model:EB 710 P)</b> |      |               |  |

|   |       |                |                |
|---|-------|----------------|----------------|
| FOB Price/Ex-factory at Port /Airport of Loading            | Innos | ₹ 2,981,000.00 | ₹ 2,981,000.00 |
| Goods & Service Tax (GST)                                   |       | ₹ 357,720.00   | ₹ 357,720.00   |
| Total Price for NEIGRIHMS rate with 5 years warranty period |       |                | ₹ 3,338,720.00 |

In words: INR Thirty Three Lakhs Thirty Eight Thousands Seven Hundred And Twenty Rupees Zero Paise

Total Price for inclusive delivered free (F.O.R) at Central stores / Department at NEIGRIHMS, Mawdiangdiang, Shillong - 793018 including loading, unloading, handling, transportation, weighbridge and other unforeseen charges.

Tenderer/ Vendors/ Contractor should note that the following terms and conditions will apply specifically in addition to the Rules and the Regulation as applicable to such purchases in the Government of India.

#### Warranty:

The Tenderer warrants comprehensively that the goods supplied under the contract is new, unused and incorporate all recent improvements in design and materials unless prescribed otherwise by the purchaser in the contract. The Tenderer further warrants that the goods supplied under the contract shall have no defect arising from design, materials (except when the design adopted and / or the material used are as per the purchaser's specifications) or workmanship or from any act or omission of the Tenderer, that may develop under normal use of the supplied goods under the conditions prevailing in India.

This warranty shall remain valid for the period mentioned above, after the goods or any portion thereof as the case may be, have been delivered to the final destination and installed and commissioned at the final destination and accepted by the purchaser in terms of the contract, unless specified otherwise in the SCC.

Upon receipt of such notice from the purchaser, the Tenderer shall, within 8 hours on a 24 (hrs) X 7 (days) X 365 (days) basis, repair or replace the defective goods or parts thereof, free of cost, at the ultimate destination. The Tenderer shall take over the replaced parts/goods after providing their replacements and no claim, whatsoever shall lie on the purchaser for such replaced parts/goods thereafter. In the event of any rectification of a defect or replacement of any defective goods during the warranty period, the same warranty for the rectified /replaced goods shall be applicable from the date such rectified / replaced goods starts functioning to the satisfaction of the purchaser.

The tender / Manufacturer /OEM has provide minimum two mandatory Periodic Preventive maintenance in a year throughout the contract period failing which action will be initiated according to terms & condition of the tender, including forfeiture of the performance bank guarantee.

#### Comprehensive Maintenance Contract (CMC):

The Purchaser/Consignee reserves the rights to enter into Annual Comprehensive Maintenance Contract (CMC) between Consignee and the Tenderer for the period after the completion of warranty period.

The consignee will enter into CMC with the Tenderer at the rates as stipulated in the contract. The payment of CMC will be made on six monthly basis after satisfactory completion of said period, duly certified by the consignee on receipt of bank guarantee for an amount equivalent to % of the CMC value in the prescribed format given in Section XV valid till 2 months after expiry of entire CMC period.

During CMC period, the Tenderer shall visit at each consignee's site for preventive maintenance including testing and calibration as per the manufacturer's service/ technical/ operational manual. The Tenderer shall



visit each consignee site as recommended in the manufacturer's manual, but at least once in 6 months commencing from the date of the successful completion of warranty period for preventive maintenance of the goods.

The payment of Annual CMC will be made against the bills raised to the consignee by the Tenderer on six monthly basis after satisfactory completion of said period, duly certified by the HOD concerned /Competent Authority and on receipt of Bank Guarantee for an amount equivalent to % of the CMC value valid till 2 months after expiry of entire CMC period. The payment will be made in Indian Rupees.

The tender / Manufacturer /OEM has provide minimum two mandatory Periodic Preventive mentainance in a year throughout the contract period failing which action will be initiated according to terms & condition of the tender, including forfeiture of the performance bank guarantee.

CMC Equipment Cost:

| S.n<br>o | Contract period   | Units | Price Per Unit | Total Cost (Exclusive of GST) |
|----------|---|-------|----------------|-------------------------------|
| 1        | <b>Slim Diameter Video Bronchoscope with 2.0 mm working channel<br/>(Make: FUJIFILM India Private Limited, Model: EB 710 P)</b> |       |                |                               |
|          | 6th year  | 1     | ₹ 89,430.00    | ₹ 89,430.00                   |
|          | 7th year  | 1     | ₹ 89,430.00    | ₹ 89,430.00                   |
|          | 8th year  | 1     | ₹ 89,430.00    | ₹ 89,430.00                   |
|          | 9th year  | 1     | ₹ 89,430.00    | ₹ 89,430.00                   |
|          | 10th year   | 1     | ₹ 89,430.00    | ₹ 89,430.00                   |

Delivery Schedule(Supply, Instalation, Testing, Commisioning with turnkey works):

For Indigenous goods or for imported goods if supplied from India: 30 days from date of Notification of Award to delivery at consignee site. (Tenderers may quote earliest delivery period).

*written 03/7/23*

For Imported goods directly from foreign:

FOB Contracts- 30 days from the date of opening of L/C. The date of delivery will be the date of Bill of Lading or Airway Bill (Tenderers may quote the earliest delivery period).

*written 03/07/23*

DDP Contracts: 30 days from the date of opening of L/C. The date of delivery will be the date of receipt by the consignee as in Consignee Receipt Certificate (Tenderers may quote the earliest delivery period).

*written 03/07/23*

Subject to the stipulation, if any, in the bidding document, the Tenderer shall be required to perform the services viz. Installation, commissioning, supervision, demonstration, complete turnkey works, providing required jigs and tools for assembling, Civil works required for the completion of the installation, training of Consignee's Doctors, Staff, operators, etc for operating and maintaining the goods, supplying the required number of operation & maintenance manual for the goods

Liquidated Damages:

If the Tenderer fails to deliver any or all of the goods or fails to perform the services within the time frame(s) incorporated in the contract, the purchaser shall, without prejudice to other rights and remedies available to the

*John Dn*

*Arumal*

*04/6/23*

purchaser under the contract, deduct from the contract price, as liquidated damages, a sum equivalent to 0.5% per week of delay or part thereof on delayed supply of goods and/or services until actual delivery or performance subject to a maximum of 10% of the contract price. Once the maximum is reached, purchaser may consider termination of the contract as per GCC 24. During the above-mentioned delayed period of supply and/or performance, the conditions incorporated under GCC sub-clause 22.4 above shall also apply. Payment shall be made subject to recoveries, if any, by way of liquidated damages or any other charges as per terms & conditions of GCC.

#### Performance Security:

Within thirty (30) days from date of the issue of Notification of Award by the purchaser, the Tenderer, shall furnish Performance Security to the purchaser for an amount equal to percent (0%) of the total value of the contract, valid for a period of sixty days (60) beyond the date of completion of all contractual obligations including the warranty obligations. In the event of any failure /default of the tenderer with or without any quantifiable loss to the government including furnishing of consignee wise Bank Guarantee for CMC security, the amount of the performance security is liable to be forfeited

Performance Security may be furnished in the form of an Account Payee, Demand Draft, Fixed Deposit Receipt / Bank Guarantee from a Commercial Bank. Bid security should be refunded to the successful bidder on receipt of Performance Security.

Bidder /Tenderer are also required to sign the rate contract agreement, within 21 (twenty one) days from the issue of the notification of award, failing which EMD /Bid Security shall be forfeited.

#### Payment:

Payment shall be made subject to recoveries, if any, by way of liquidated damages or any other charges as per terms & conditions of GCC. Payment for domestic goods shall be made in Indian rupees as specified in the GCC clause 21.1. For Imported goods, 90% of the net FOB /CIF price (less Indian Agency Commission) as the case may be, through irrevocable, non-transferable Letter of Credit (LC) opened in favour of the Foreign Principal in a bank in his country and remaining as per the terms & conditions indicated in GCC clause 21.

#### Corrupt or Fraudulent Practices /Code of Integrity:

It is required by all concerned namely the Consignee/Tenderers/Suppliers etc to observe the highest standard of ethics during the procurement and execution of such contracts and to abide by the Code of Integrity Act, as per GFR 2017. In pursuance of this policy, the Purchaser: - defines, for the purposes of this provision, the terms set forth below as follows: "corrupt practice" means the offering, giving, receiving or soliciting of any thing of value to influence the action of a public official in the procurement process or in contract execution; and "fraudulent practice" means a misrepresentation of facts in order to influence a procurement process or the execution of a contract to the detriment of the Purchaser, and includes collusive practice among Tenderers (prior to or after Tender submission) designed to establish Tender prices at artificial non-competitive levels and to deprive the Purchaser of the benefits of free and open competition; Will reject a proposal for award if it determines that the Tenderer recommended for award has engaged in corrupt or fraudulent practices in competing for the contract in question; Will declare a firm ineligible, either indefinitely or for a stated period of time, to be awarded a contract by the purchaser if it at any time determines that the firm has engaged in corrupt or fraudulent practices in competing for or in executing the contract

#### Settlement of Disputes

If there is any dispute or differences, the same may be referred to Director, NEIGRIHMS. Director, NEIGRIHMS or his authorized representative shall be the final authority in all disputes and decision taken by



the authority will be binding on all concerned. Therefore, the jurisdiction in respect of settlement of disputes in Stores & Civil contracts shall be as per the Commercial Courts, Commercial Division and Commercial Appellate Division of High Courts (Amendment) Ordinance 2018, wherein the provision for pre-institution mediation, has been made mandatory in respective cases by the parties to the disputes.

Name of the Consignee:

Director, North Eastern Indira Gandhi Regional Institute of Health and Medical Sciences, Mawdiangdiang, Shillong -793018 (Meghalaya), INDIA

All other terms & conditions are as per Tender Enquiry No / Offer No.: GEM/2023/B/3162547 / NA

(Kindly refer to the tender / bid document for all required Annexures / Proforma/Forms)

Validated By,  
Harendra dey  
15-06-2023 17:07:18

Yours faithfully,

  
Stores & Procurement Officer,  
For and on behalf of Director, NEIGRIHMS, Shillong  
**Store & Procurement Officer**  
**NEIGRIHMS Shillong-18**

Copy to:


Indenting Officer / Inspection authority- Head / Incharge, Department / Section of Tuberculosis and Respiratory Diseases  
Central / Ancillary Store  
Biomedical Engineer  
Purchase Order Master / Relevant File  
Stores Section Record

① Dr Vijay ② Mr J K D - Medicine  
② MS / MS / re Central Store / BMS  
③ Dr M / Dr J K D - Medicine  
④ Mr K - Medicine  
⑤ Mr K - Medicine  
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Enclosed:

- Annexure : Technical Specification
- Annexure : Tender Form (Section -X)
- Annexure : Compliance Statement
- Annexure : Manufacturer's Authorization / Acceptance Letter
- Annexure : Others

  
Store & Procurement Office  
NEIGRIHMS Shillong-18

**Technical Specification for Slim Diameter Bronchoscope with 2.0 mm working channel:**

**1. Video Bronchoscope:**

Should have following specifications:

1. Lighter and possess high resolution image quality.
2. Should have latest CMOS technology.
3. Scope should have image enhancement function
4. Fully immersible in disinfectant solution.
5. Should have High-definition image quality.
6. Two or more no. of remote-control switches on control body.
7. Scope should have rotatable insertion tube function.
8. Compatible with leakage testing device Manual/Automatic.
9. Should be compatible with Existing Video Processor & Light Source (VP-7000 & BL-7000) installed in the Department.

Field of view: 120 degree or more

Direction of view: 0-degree, forward viewing

Depth of field: 2 to 50 mm or better

Distal end outer diameter: 4.1 mm or less

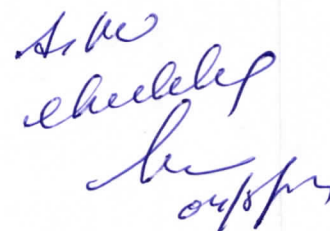
Insertion tube outer diameter: 4.1 mm or less

Tip Bending rage: Up 210 deg & more, down 130 deg & more

Working length: 600 mm or more

Channel inner diameter: 2.0 mm or more



**Store & Procurement Officer  
NEIGRIHMS Shillong-18**



**MANUFACTURER'S AUTHORISATION FORM**

Dated: 10-03-2023

To,  
Deputy Director  
NEIGRIHMS,  
Mawdiangdiang,  
Shillong- 793018

Ref. Your GeM Bid Number: GEM/2023/B/3162547 Dated: 22-02-2023 for "Slim Diameter Video Bronchoscope with 2.0 mm working channel".

Dear Sir,

We, M/s Fujifilm India Private Limited (Fully owned Indian Subsidiary of Fujifilm Corporation, Japan) who are proven and reputable manufacturers of "**Slim Diameter Video Bronchoscope with 2.0 mm working channel**" having factories at 700 Konakamacho, Sano City, Tochigi Prefecture, 327-0001, Japan, hereby authorise **Messrs SPSS Mediline, 88, Flyover Market, Defence Colony, New Delhi – 110 024 (India)** to submit a tender, 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.

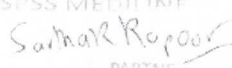
We further confirm that no supplier or firm or individual other than Messrs. **SPSS Mediline, New Delhi (India)** is authorised to submit a tender, process the same further and enter into a contract with you against your requirement as contained in the above referred TE documents for the above goods manufactured by us.

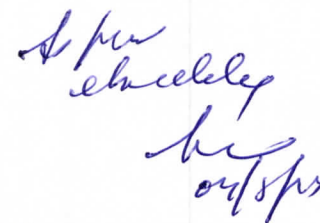
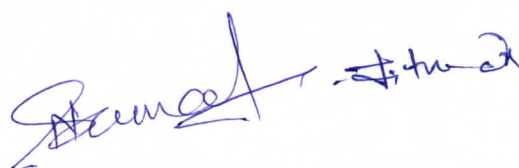
We also hereby extend our full warranty, CMC as applicable as per relevant clauses of the Tender Document for the goods and services offered for supply by the above firm against this TE document.

Yours faithfully,

For Fujifilm India Pvt. Ltd.

  
Pankaj Sirohi  
Sales Head- Govt. Business  
Mobile-08130289860,  
Email- [Pankaj.sirohi@fujifilm.com](mailto:Pankaj.sirohi@fujifilm.com)

For SPSS MEDILINE  
  
PARTNER



Store & Procurement Officer  
NEIGRIHMS Shillong-18

**FUJIFILM INDIA PRIVATE LIMITED**

**Corporate Office:** Unitech Cyber Park, Unit No. 801-807, 8th Floor, Tower C, Sector 39, Gurugram-122001, Haryana Telephone: +91-12 4325500, Fax: +91-124-4325555, Website: [www.fujifilm.in](http://www.fujifilm.in), Email: [tenders.ffin@fujifilm.com](mailto:tenders.ffin@fujifilm.com) CIN:U24233DL2007PTC171054

**Registered Office:** Business Centre Office No. 521, Level-V, Caddie Commercial Tower, Hospitality District Aerocity IGI Airport, New Delhi 110037. Telephone: +91-11-66544932

# TECHNICAL COMPLIANCE

Bid Number: GEM/2023/B/3162547 Dated: 22-02-2023

Slim Diameter Bronchoscope with 2.0 mm working channel

| S. No. | Technical Specifications  | Qty  | Our Compliance<br>Make : FUJIFILM (Japan) |
|--------|---|------|---|
|        | <b>Video Bronchoscope:</b>  | 1No. | Model : EB-710P                           |
| 1      | Should have following specifications:                             |      | Full Compliance                           |
| 2      | Lighter and possess high resolution image quality.                |      | Full Compliance                           |
| 3      | Should have latest CMOS technology.                               |      | Full Compliance                           |
| 4      | Scope should have image enhancement function                      |      | Full Compliance                           |
| 5      | Fully immersible in disinfectant solution.                        |      | Full Compliance                           |
| 6      | Should have High-definition image quality.                        |      | Full Compliance                           |
| 7      | Two or more no. of remote-control switches on control body.       |      | Full Compliance                           |
| 8      | Scope should have rotatable insertion tube function.              |      | Full Compliance                           |
| 9      | Compatible with leakage testing device Manual/Automatic.          |      | Full Compliance                           |
| 10     | Should be compatible with Existing Video Processor & Light Source |      | Full Compliance                           |
| 11     | Field of view: 120 degree or more                                 |      | Full Compliance                           |
| 12     | Direction of view: 0-degree, forward viewing                      |      | Full Compliance                           |
| 13     | Depth of field: 2 to 50 mm or better                              |      | Full Compliance                           |
| 14     | Distal end outer diameter: 4.1 mm or less                         |      | Full Compliance                           |
| 15     | Insertion tube outer diameter: 4.1 mm or less                     |      | Full Compliance                           |
| 16     | Tip Bending rage: Up 210 deg & more, down 130 deg & more          |      | Full Compliance                           |
| 17     | Working length: 600 mm or more                                    |      | Full Compliance                           |
| 18     | Channel inner diameter: 2.0 mm or more                            |      | Full Compliance                           |

*[Signature]*

*[Signature]*

Store & Procurement Officer  
NEIGRIHMS Shillong-18



March 10, 2023

NEIGRIHMS  
Mawdiangdiang  
Shillong - 793 018.

Ref: Your Bid Number: GEM/2023/B/3162547 dated 23.02.2023 for Slim Diameter Video Bronchoscope with 2.0 mm working channel

### SCOPE OF SUPPLY

| S/N | ITEM DESCRIPTION       | MODEL   | Qty. |
|-----|------------------------|---------|------|
|     |                        |         |      |
|     | Make : FUJIFILM, JAPAN |         |      |
| 1   | VIDEO BRONCHOSCOPE     | EB-710P | 1    |

For SPSS MEDILINE  
Sankar Roychowdhury  
*[Signature]*

*[Signature]*  
Sankar Roychowdhury

Store & Procurement Officer  
NEIGRIHMS Shillong-18

## Contract | अनुबंध

GeM

Contract No | अनुबंध क्रमांक: GEMC-511687792767330

Generated Date | अनुबंध तिथि: 04-May-2023

Bid/RA/PBP No. | बोली/आरए/पीबीपी संख्या: GEM/2023/B/3162547

## Organisation Details | संगठन विवरण

Type | प्ररूप: Central Autonomous  
Ministry | मंत्रालय: Ministry of Health and Family Welfare  
Department | विभाग: Department of Health and Family Welfare  
Organisation Name | संगठन का नाम: North Eastern Indira Gandhi Regional Institute of Health and Medical Sciences (NEIGRIHMS)  
Office Zone | कार्यालय क्षेत्र: Neigrihms, Shillong

## Buyer Details | खरीदार विवरण

Designation | पद: Stores and Procurement Officer  
Contact No. | संपर्क नंबर: 0364-2539032-213  
Email ID | ईमेल आईडी: harendra.dey@nic.in  
GSTIN | जीएसटीआईएन: N  
Address | पता: P.O. NEIGRIHMS, Mawdiangdiang, Shillong, EAST KHASI HILLS, MEGHALAYA-793018, India

## Financial Approval Detail | वित्तीय स्वीकृति विवरण

IFD Concurrence | आईएफडी सहमति: Yes  
Designation of Administrative Approval | प्रशासनिक अनुमोदन का पदनाम: Director, S&P/TB-01/2022-23, Addon Scope for existing EBUS unit  
Designation of Financial Approval | वित्तीय अनुमोदन का पदनाम: DDA & DFA, Approved Agenda C-17, Of 65th PC, CDN-C-16/23-24, 17/04/2023

## Paying Authority Details | भुगतान प्राधिकरण विवरण

Role: PAO  
Payment Mode | भुगतान का तरीका: Offline  
Designation | पद: A Accounts officer  
Email ID | ईमेल आईडी: accounts.neigrihms@nic.in  
GSTIN | जीएसटीआईएन: N  
Address | पता: P.O. NEIGRIHMS, Mawdiangdiang, Shillong, KHASI HILLS EAST, MEGHALAYA-793018, India

## Seller Details | विक्रेता विवरण

GeM Seller ID | जेम विक्रेता आईडी: BB3318000097746  
Company Name | कंपनी का नाम: SPSS MEDILINE  
Contact No. | संपर्क नंबर: 09999969798  
Email ID | ईमेल आईडी: spssmediline@gmail.com  
Address | पता: # 88, FLYOVER MARKET, DEFENCE COLONY, NEW DELHI, DELHI-110024, -  
MSME verified | एमएसएमई सत्यापित: No  
MSME Registration number | एमएसएमई पंजीकरण संख्या: DL08D0029148  
MSE Social Category | एमएसई सामाजिक श्रेणी: General  
MSE Gender | एमएसई लिंग श्रेणी: Male  
GSTIN | जीएसटीआईएन: 07ACFFS4339H1ZZ

\*GST / Tax invoice to be raised in the name of | जिसके नाम के पक्ष में GST/TAX इनवॉइस पेश किया जाएगा - Buyer

## Product Details | उत्पाद विवरण

| #  | Item Description   आइटम विवरण   | Ordered Quantity   आइटम विवरण | Unit   इकाई | Unit Price (INR)   इकाई मूल्य (INR) | Tax Bifurcation (INR)   कर विभाजन (INR)   | Price (Inclusive of all Duties and Taxes in INR)   मूल्य (INR) में सभी शुल्क और कर सहित) |
|--|---|-------------------------------|-------------|-------------------------------------|---|--|
| 1  | <p>Product Name   उत्पाद का नाम: Fujifilm Slim Diameter Video Bronchoscope with 2.0 mm working channel<br/>Brand   ब्रांड: FUJIFILM<br/>Brand Type   ब्रांड प्रकार: Registered Brand<br/>Catalogue Status   कैटलॉग की स्थिति: Catalogue not verified by OEM<br/>Selling As   कैसे बेचा जा रहा है: Reseller not verified by OEM<br/>Category Name &amp; Quadrant   श्रेणी का नाम और चतुर्थांश: Fujifilm Slim Diameter Video Bronchoscope with 2.0 mm working channel (Q3)<br/>Model   मॉडल: EB-710P<br/>HSN Code   एचएसएन कोड: HSN not specified by seller</p> | 1                             | pieces      | 3,338,720                           | <p>GST   जीएसटी (12%): 357,720<br/>GST Cess 1   जीएसटी उपकर 1 (0%): 0<br/>GST Cess 2   जीएसटी उपकर 2 (0 per accounting unit): 0<br/>Input Tax Credit (ITC) on GST   जीएसटी पर इनपुट टैक्स क्रेडिट (आईटीसी):<br/>-<br/>ITC on GST Cess 1   जीएसटी उपकर पर आईटीसी 1: -<br/>ITC on GST Cess 2   जीएसटी उपकर पर आईटीसी 2: -</p> | 3,338,720  |
| Total Order Value   कुल ऑर्डर मूल्य (in INR) |   |                               |             |                                     |   | 3,338,720  |

## Consignee Detail | परेषिती विवरण

| S.No   क्र.सं. | Consignee   परेषिती   | Item   वस्तु                              | Lot No.   लॉट नंबर | Quantity   मात्रा | Delivery Start After   दिनांक के बाद डिलीवरी शुरू करना है | Delivery To Be Completed By   वितरण पूरा कब तक करना है |
|----------------|---|---|--------------------|-------------------|---|--|
| 1              | <p>Designation   पद: -<br/>Email ID   ईमेल आईडी: con18.neigrihms.ml@gembuyer.in<br/>Contact   संपर्क: 0364-2538044-</p> | Fujifilm Slim Diameter Video Bronchoscope |                    | 1                 | 04-May-2023   | 03-Jul-2023  |

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GSTIN | जीएसटीआईएन : -  
Address | पता : P.O. NEIGRIHMS, Mawdiangdiang, Shillong,  
EAST KHASI HILLS, MEGHALAYA-793018, India

with 2.0 mm working  
channel

## Product Specification for Fujifilm Slim Diameter Video Bronchoscope with 2.0 mm working channel

| Specification   विनिर्देश | Sub-Spec   उप-विनिर्देश | Value   मूल्य |
|---------------------------|-------------------------|---------------|
| Custom Specification      | Custom Specification    | Yes           |

## Comprehensive maintenance charges for | व्यापक रखरखाव के लिए शुल्क Fujifilm Slim Diameter Video Bronchoscope with 2.0 mm working channel

| Service Year   सेवा वर्ष  | CMC Percentage   सीएमसी प्रतिशत | Tax Bifurcation   कर द्विभाजन   |
|---|---------------------------------|---|
| CMC charges for 1 st year after warranty period in % of cost of equipment | 3%                              | GST   जीएसटी: 12%<br>GST Cess 1   जीएसटी उपकर 1: 0%<br>Input Tax Credit (ITC) on GST   जीएसटी पर इनपुट टैक्स क्रेडिट (आईटीसी): -<br>ITC on GST Cess 1   जीएसटी उपकर पर आईटीसी 1 : - |
| CMC charges for 2 nd year after warranty period in % of cost of equipment | 3%                              |   |
| CMC charges for 3 rd year after warranty period in % of cost of equipment | 3%                              |   |
| CMC charges for 4 th year after warranty period in % of cost of equipment | 3%                              |   |
| CMC charges for 5 th year after warranty period in % of cost of equipment | 3%                              |   |

## Seller Specification Document | विक्रेता विशिष्टता दस्तावेज़:

|   |   |
|---|---|
| 1. <a href="#">SpecificationDocument1</a> | mkp.gem.gov.in/catalog_data/catalog_support_document/18/54/531/CatalogAttrs/SpecificationDocument/2023/3/9/2023_03_09_12_18_55_slim_2023-02-20-14-28-55_a62ca9_2023-03-09-12-18-58_b5a9d1542df8a<br>f28a616925c2f3a7c1e.pdf |
|---|---|

## Buyer Specification Document | खरीदार विशिष्टता दस्तावेज़:

|  |  |
|--|--|
| 1. <a href="#">SpecificationDocument</a> | mkp.gem.gov.in/catalog_data/catalog_support_document/buyer_documents/52738/54/78/703/CatalogAttrs/SpecificationDocument/2023/2/20/slim_2023-02-20-14-28-55_a62ca9e1caef547d3f8bcb99330d979.pdf |
|--|--|

## Corrigendum | शुद्धिपत्र

1. Extended Upto | तक बढ़ाया गया : 2023-03-16 14:00:00

## Additional Clauses for CMC | सीएमसी के लिए अतिरिक्त खंड

- 1.CMC shall include preventive maintenance including calibration as per technical/ service /operational manual of the manufacturer, service charges and spares, after satisfactory completion of Warranty. During the CMC period commencing from date of the successful completion of warranty period, Service personnel shall visit each consignee site as recommended in the manufacturer's technical/ service /operational manual, at least once in six months or as per user requirement. Cost of consumables shall not be included in CMC.Further there will be 98% uptime warranty during CMC period on 24 (hrs) X 7 (days) X 365 (days) basis, with penalty, to extend CMC period by double the downtime period.
- 2.CMC charges to be indicated as percentage of cost of equipment quoted for each year after the warranty period.
- 3.GST shall be included in the CMC Charges quoted.
- 4.Cost of CMC will be added for Ranking/Evaluation purpose with depreciation formula.A 10% discounting rate per year shall be applied on CMC Charges for price evaluation on Net Present Value.
- 5 The payment of CMC will be made on quarterly basis after satisfactory completion of said period, duly certified by end user.
- 6.While creating a bid or RA, buyers shall indicate whether CMC is required against Yes/No" options. If CMC Charges are included, an option for number of years for CMC required after the warranty period shall be available.Under this option up to 10 years can be chosen for CMC charges beyond warranty period.
- 7.In case the bid has a provision for CMC, the warranty of the product will also be deemed to have been converted into Comprehensive warranty including preventive maintenance and calibration as per technical/ service /operational manual of the manufacturer, service charges and spares, during the Warranty Period also. Sellers are therefore advised to include the cost of Comprehensive Warranty including spares (excluding consumables) also in product Cost.
- 8.The CMC functionality shall be available in bid only and no direct RA shall be applicable.In case of bid to R/A decrement rules shall be applicable on total price inclusive of CMC charges. Bunching of products shall not be available while creating bids with CMC charges.

8.1.Buyer shall indicate number of years of warranty by selecting different options available in the field depending on warranty parameter applicable in category parameters for the equipment. No. of years of warranty indicated here shall supersede the warranty period indicated elsewhere in bid or product specifications. The Seller while participating in Bid/RA will get fields to indicate CMC charges as percentage depending on number of years of CMC selected by Buyer. The following shall be applicable, if 5 year CMC selected:

- CMC charges for 1st year after warranty period- Percentage to be indicated- A1
- CMC charges for 2nd year after warranty period- Percentage to be indicated- A2
- CMC charges for 3rd year after warranty period - Percentage to be indicated- A3
- CMC charges for 4th year after warranty period - Percentage to be indicated- A4
- CMC charges for 5th year after warranty period - Percentage to be indicated- A5

Similarly, A6 to A10 are to be indicated for 6th to 10th year of CMC if applicable.

8.2.The calculation of CMC Charges shall take into account the number of years of warranty and duration of CMC as specified while creating bid.

8.3.In the price evaluation, the system shall provide function to calculate the cost of each equipment by formula indicated below including CMC and then show the inter-se-ranking of the bidders. The following are the variables

- (i) Number of years for which CMC required.

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(ii) Number of years of product warranty

The formula for calculating total cost including CMC charges shall be as under:

Total Cost for evaluation=

$C + C * ((A1/100)/(1.10^n) + (A2/100)/(1.10^{n+1}) + (A3/100)/(1.10^{n+2}) + (A4/100)/(1.10^{n+3}) + (A5/100)/(1.10^{n+4}))$  and so on

C – Cost for equipment quoted and n shall be number of years of product warranty specified.

If 2 year warranty specified, n shall be 2 and if 5 year warranty specified, n shall be 5. A1, A2, A3, A4 & A5 shall depend on how many years CMC selected. For 3 year CMC, only A1, A2 and A3 factors are to be taken into account and A4 and A5 will not be applicable.

8.4 CMC charges offered for each subsequent year should be same or higher than preceding year.

8.5 The CMC charges shall be offered within range of 3 to 10% of cost of equipment.

9. Since CMC charges are to be paid only later for each year during CMC period, applicable performance guarantee amount after placement of contract shall be based on the cost of equipment excluding the cost of CMC Charges.

10. Performance bank guarantee applicable for CMC is to be submitted at start of the CMC and shall be applicable between 2.5% to 5% as specified in bid on total CMC Charges. The PBG submitted after award of contract shall be released only after new PBG for the CMC period is submitted and accepted by buyer/consignee after due verification. Bank guarantee for CMC is to remain valid till completion of CMC period plus one year. The bank guarantee for CMC shall be submitted to buyer directly. In case, seller fails to submit the PBG or does not provide services for the CMC contract after expiry of warranty period then PBG of equipment shall be forfeited.

11. In case of splitting of order quantity, equipment cost and CMC charges offered by L1 bidder shall be matched by higher quoting eligible bidders on one-to-one basis. The equipment cost and CMC charges (year to year) shall be matched individually.

12. The CMC Contract shall be an offline contract to be handled by buyer. The payment of CMC will be made on quarterly basis after satisfactory completion of said period, duly certified by end user and scope of CMC will be as per para 1 above.

#### ePBG Detail | ईपीबीजी विवरण

|  |                |
|--|----------------|
| Advisory Bank   सलाहकार बैंक :             | Bank Of Baroda |
| ePBG Percentage(%)   ईपीबीजी प्रतिशत (%) : | 3.00           |

The bidder shall furnish ePBG as applicable as per bid's terms and conditions | बोली लगाने वाले को बोली के नियमों और शर्तों के अनुसार लागू ईपीबीजी प्रस्तुत करना होगा

#### General Clauses w.r.t RCM/FCM | आरसीएम/एफसीएम के संबंध में सामान्य खंड

- Where ever RCM is applicable, for sellers (Regular GST registered seller who opted out of FCM as per notifications of GST like GTA, unregistered seller), Buyer have liability of paying the GST and GST cess to the government on the specified rate mentioned by them in this contract. Seller will invoice buyer with Zero GST and GST cess.
- For Registered sellers as per FCM, rates will be inclusive of prescribed rate of GST and GST cess. ITC available to buyer as shown in the bid document have been applied while evaluating the bids. Seller has liability of paying the GST and GST cess to the govt and same will be charged from buyer while invoice.
- For Registered sellers who opted for RCM while quoting for specified category under section 9(3) like GTA rates will be exclusive of GST and GST cess. GST and GST cess as indicated by the buyer in the bid document payment of GST and GST Cess will be the liability of buyer.
- For Unregistered sellers Liability of payment of GST and GST cess is in Buyers scope. GST and GST cess as indicated by the buyer in the bid document will be the liability of buyer. Unregistered seller will invoice buyer with zero GST and Zero GST cess.
- For sellers under Composition Scheme: There is no liability of payment of GST and GST cess in Buyers cope. Seller will invoice Zero GST and GST cess in the invoice to buyer.

#### Terms and Conditions | नियम और शर्तें

##### 1. General Terms and Conditions-

- This contract is governed by the General Terms and Conditions, conditions stipulated to this Product/Service as provided in the Marketplace.
- This Contract between the Seller and the Buyer, is for the supply of the Goods and/ or Services, detailed in the schedule above, in accordance with the General Terms and Conditions (GTC) unless otherwise superseded by Goods / Services specific Special Terms and Conditions (STC) and/ or BID/Reverse Auction Additional Terms and Conditions (ATC), as applicable

##### 2. Buyer Added Bid Specific Terms and Conditions-

- Buyer Added Bid Specific ATC:  
Buyer Added text based ATC clauses

**File No:-NEIGR/S&P/ S-01/2022-23**

**Agenda 7 of IPC-07/2022-23.**

#### Scope of work & Document details

|   |   |
|---|---|
| A | Following mandatory documents must be attached in the bid document as specified, failing which bid will be treated as "Non-Responsive"                                    |
| 1 | Cost of spares, consumables and accessories not covered under warranty and CMC period shall be offered as percentage value of the system/Unit in the Technical Bid ATC1/2 |
| 2 | Documents with regard to Details compliance statement to be attached At "Additional Doc   |

  
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|   |  |
|---|--|
|   | 2(Requested in ATC)"   |
| 3 | Documents with regard to Original Literature, Product catalogue, Technical datasheet from the firm/O.E.M with Highlighting as per the technical specification must attach At "Additional Doc 3(Requested in ATC)"  |
| 4 | Documents with regard to list of Offering/Quoted items mentioning make, model & quantity of each items must be "Additional Doc 4(Requested in ATC)"  |
| B | Warranty and Maintenance   |
| 1 | Warranty for 5 years followed by CMC for 5 years including Spares & service for all the items supplied in this particular tender including third-party items and turn key works .  |
| 2 | Mandatory 2 PMs / Year with unlimited breakdown calls has to be attended by the Bidder/manufacturer throughout the warranty & CMC period at site.i.e. NEIGRIHMS, SHILLONG.   |
| 3 | Duly signed Mandatory PM reports has to be submitted periodically, failing which necessary action will be initiated as per term& condition of the tender.  |
| 3 | E-bidder have to adhere to Government of India, Ministry of Finance, PPD division Public procurement order OM F.No.6/18/2019-PPD dated 23rd july,2020 inserting Rule 144(Xi)in GFR 2017 ,No 1 dated: 23/7/2020 and subsequent Orders No 2 & 3 or as amended from time to time , failing which the bids shall be treated as non-responsive. |

#### B.Buyer Added Bid Specific Terms and Conditions

##### 1. Generic

End User Certificate: Wherever Bidders are insisting for End User Certificate from the Buyer, same shall be provided in Buyer's standard format only.

##### 2. Generic

Experience Criteria: The Bidder or its OEM {themselves or through reseller(s)} should have regularly, manufactured and supplied same or similar Category Products to any Central / State Govt Organization / PSU / Public Listed Company for 3 years before the bid opening date. Copies of relevant contracts to be submitted along with bid in support of having supplied some quantity during each of the year. In case of bunch bids, the primary product having highest value should meet this criterion.

##### 3. Generic

IT equipment shall be IPv6 ready from day one.

##### 4. Generic

Installation, Commissioning, Testing, Configuration, Training (As applicable as per scope of supply) is to be carried out by OEM / OEM Certified resource or OEM authorized Reseller.

##### 5. Generic

Upload Manufacturer authorization: Wherever Authorized Distributors are submitting the bid, Manufacturers Authorization Form (MAF)/Certificate with OEM details such as name, designation, address, e-mail Id and Phone No. required to be furnished along with the bid.

##### 6. Generic

The successful bidder has to supply all essential accessories required for the successful installation and commissioning.

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NEIGRIHMS SHILLONG

ning of the goods supplied. Besides standard accessories as per normal industry practice, following accessories must be part of supply and cost should be included in bid price: All the items and accessories as per Technical Specification.

7. Generic

The Buyer has an existing set up / inventory of similar products. The offered / supplied product must be compatible with existing system. The bidder has to ensure Compatibility of the supplied items or shall have to include in the supply the necessary hardware / software to make them compatible at no extra cost to the buyer. The details of items with which compatibility is required are as under: all the spares Including UPS, PC, battery, Printer, Probes & upgradation of System Software & third party Software

8. Scope of Supply

Scope of supply (Bid price to include all cost components) : Supply Installation Testing Commissioning of Goods, Training of operators and providing Statutory Clearances required (if any)

9. Turnover

**Bidder Turn Over Criteria:** The minimum average annual financial turnover of the bidder during the last three years, ending on 31st March of the previous financial year, should be as indicated in the bid document. Documentary evidence in the form of certified Audited Balance Sheets of relevant periods or a certificate from the Chartered Accountant / Cost Accountant indicating the turnover details for the relevant period shall be uploaded with the bid. In case the date of constitution / incorporation of the bidder is less than 3 year old, the average turnover in respect of the completed financial years after the date of constitution shall be taken into account for this criteria.

10. Turnover

**OEM Turn Over Criteria:** The minimum average annual financial turnover of the OEM of the offered product during the last three years, ending on 31st March of the previous financial year, should be as indicated in the bid document. Documentary evidence in the form of certified Audited Balance Sheets of relevant periods or a certificate from the Chartered Accountant / Cost Accountant indicating the turnover details for the relevant period shall be uploaded with the bid. In case the date of constitution / incorporation of the OEM is less than 3 year old, the average turnover in respect of the completed financial years after the date of constitution shall be taken into account for this criteria. In case of bunch bids, the OEM of CATEGORY RELATED TO primary product having highest bid value should meet this criterion.

11. OEM

**IMPORTED PRODUCTS:** In case of imported products, OEM or Authorized Seller of OEM should have a registered office in India to provide after sales service support in India. The certificate to this effect should be submitted.

12. Purchase Preference (Centre)

As per DPIIT notification at the time of e-tender, bidding or solicitation the bids shall be required to indicate percentage of local content and provide self-certification (by Director/ Company Secretary) and also give details of the location/s at which value addition is made". Since the bidder here is not the local supplier, the same was required to be obtained from the "Class-I local supplier /Class II local supplier"

Further the details of Calculations of local content areas under:

Question 1. How to calculate Local Content?

Answer: Para 2 of the PPP-MII Order, 2017 (as amended on 16.09.2020) defines local content as

Local content' means the amount of value added in India which shall, unless otherwise prescribed by the Nodal Ministry, be the total value of the item procured (excluding net domestic indirect taxes) minus the value of imported content in the item (including all customs duties) as a proportion of the total value, in percent.

Mathematically,

Local content = (Sale price - Value of imported content) \* 100/ Sale price

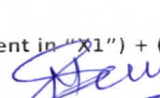
Where, "Sale price" means price excluding net domestic indirect taxes and "Value of imported content" means price of imported content inclusive of all customs duties

Question2. How to calculate Local Content in bids involving supply of multiple items from single bidder?

Answer: In case of bids requiring supply of multiple items (say "X1", "X2" and "X3") by a single bidder, the local content in the bid shall be

Local content = ((Sale price of "X1" - Value of imported content in "X1") + (Sale price of "X2" - Value of imported content in "X2") + (Sale price of "X3" - Value of imported content in "X3")) \* 100 / (Sale price of "X1" + Sale price of "X2" + Sale price of "X3")





Stores & Procurement Officer  
NEIGRIHNS Shillong



content in "X2") + (Sale price of "X3" - Value of imported content in "X3")) \* 100/ (Sale price of "X1" + Sale price of "X2" + Sale price of "X3")

13. Service & Support

Availability of Service Centres: Bidder/OEM must have a Functional Service Centre in the State of each Consignee's Location in case of carry-in warranty. (Not applicable in case of goods having on-site warranty). If service centre is not already there at the time of bidding, successful bidder / OEM shall have to establish one within 30 days of award of contract. Payment shall be released only after submission of documentary evidence of having Functional Service Centre.

14. Service & Support

Dedicated /toll Free Telephone No. for Service Support : BIDDER/OEM must have Dedicated/toll Free Telephone No. for Service Support.

15. Service & Support

Escalation Matrix For Service Support : Bidder/OEM must provide Escalation Matrix of Telephone Numbers for Service Support.

16. Certificates

Bidder's offer is liable to be rejected if they don't upload any of the certificates/ documents sought in the Bid document, ATC and Corrigendum if any.

17. Certificates

The bidder or the OEM of the offered products must have BIS/WHO-GMP/ CDSCO Indian certification or alternate certification as recognized by Government of India

18. Certificates

Material Test Certificate Should Be Sent Along with The Supply. The Material Will Be Checked by Buyer's Lab & the Results of the Lab will be the Sole Criteria for Acceptance of the Item.

19. Certificates

The bidder is required to upload, along with the bid, all relevant certificates such as BIS licence, type test certificate, approval certificates and other certificates as prescribed in the Product Specification given in the bid document.

20. Certificates

To be eligible for award of contract, Bidder / OEM must possess following Certificates / Test Reports on the date of bid opening (to be uploaded with bid): All the quality & electrical safety certificates .

21. Warranty

Bidder / OEM has to give an undertaking that after expiry of warranty period, it will provide Comprehensive Maintenance Service for next 5 years for the offered products at the rate not more than 5% of contract price per annum. Buyer reserves the right to enter into a CMC agreement with the Successful Bidder / OEM after expiry of the Warranty period at above mentioned rate and the payment for the CMC charges would be made Biannually after rendering of the CMC Services of the relevant CMC period. Performance Security of the successful bidder shall be forfeited if it fails to accept the CMC contract when called upon by the buyer. CMC would include cost of all the spares including UPS, PC, battery, Printer, Probes & upgradation of System Software & third party Software (Upload the undertaking). The original Performance Security of contract will be returned only after submission and verification of AMC Performance Security for 5% of total CMC value valid up to CMC period plus 2 months (if there is no other claim).

22. Warranty

Warranty period of the supplied products shall be 5 years from the date of final acceptance of goods or after completion of installation, commissioning & testing of goods (if included in the scope of supply), at consignee location. OEM Warranty certificates must be submitted by Successful Bidder at the time of delivery of Goods. The seller should guarantee the rectification of goods in case of any break down during the guarantee period. Seller should have well established Installation, Commissioning, Training, Troubleshooting and Maintenance Service group in INDIA for attending the after sales service. Details of Service Centres near consignee destinations are to be uploaded along with the bid.

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23. Warranty

Over and above the normal Warranty terms as per GeM GTC, the successful bidder / OEM shall have to provide Comprehensive Warranty during the entire Standard warranty period as per contract. : The comprehensive warranty shall be covering the following scope all the spares including UPS, PC, battery, Printer, Probes & upgradation of System Software & third party Software (Upload an undertaking with the bid confirming compliance by the bidder if Bidder is taking onus of this compliance. In case OEM is taking onus of this compliance, OEM undertaking is to be uploaded along with Bidder undertaking)

24. Warranty

Successful bidder will have to ensure that adequate number of dedicated technical service personals / engineers are designated / deployed for attending to the Service Request in a time bound manner and for ensuring Timely Servicing / rectification of defects during warranty period, as per Service level agreement indicated in the relevant clause of the bid.

25. Warranty

Timely Servicing / rectification of defects during warranty period: After having been notified of the defects / service requirement during warranty period, Seller has to complete the required Service / Rectification within 3 days' time limit. If the Seller fails to complete service / rectification with defined time limit, a penalty of 0.5% of Unit Price of the product shall be charged as penalty for each week of delay from the seller. Seller can deposit the penalty with the Buyer directly else the Buyer shall have a right to recover all such penalty amount from the Performance Security (PBG). Cumulative Penalty cannot exceed more than 10% of the total contract value after which the Buyer shall have the right to get the service / rectification done from alternate sources at the risk and cost of the Seller besides forfeiture of PBG. Seller shall be liable to re-imburse the cost of such service / rectification to the Buyer.

26. Past Project Experience

For fulfilling the experience criteria any one of the following documents may be considered as valid proof for meeting the experience criteria:

- a. Purchase Order copy along with Invoice(s) with self-certification by the bidder that supplies against the invoices have been executed.
- b. Execution certificate by client with order value.
- c. Any other document in support of order execution like Third Party Inspection release note, etc.

27. Past Project Experience

The Bidder / OEM (themselves or through reseller(s)), should have executed project for supply and installation / commissioning of same or similar Category Products during preceding 3 financial years (i.e. current year and two previous financial years) as on opening of bid, as per following criteria:

- (i) Single order of at least 35% of estimated bid value; or
- (ii) Two orders of at least 20% each of estimated bid value; or
- (iii) Three orders of at least 15% each of estimated bid value.

Satisfactory Performance certificate issued by respective Buyer Organization for the above Orders should be uploaded with bid. In case of bunch bids, the Category related to primary product having highest bid value should meet this criterion

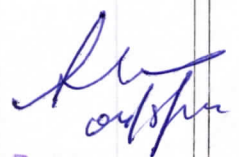
28. Forms of EMD and PBG

Bidders can also submit the EMD with Account Payee Demand Draft in favour of NEIGRIHMS EMD SECURITY DEPOSITS payable at MAWDIANGDIANG, SHILLONG-793018, MEGHALAYA. Bidder has to upload scanned copy / proof of the DD along with bid and has to ensure delivery of hardcopy to the Buyer within Bid End date & time / Bid Opening date & time.

29. Forms of EMD and PBG

Bidders can also submit the EMD with Fixed Deposit Receipt made out or pledged in the name of A/C (Name of the Buyer). The bank should certify on it that the deposit can be withdrawn only on the demand or with the sanction of the pledgee. For release of EMD, the FDR will be released in the favour of the bidder by the Buyer after making endorsement on the back of the FDR duly signed and stamped along with covering letter. Bidder has to upload scanned copy / proof of the FDR along with bid and has to ensure delivery of hardcopy to the Buyer within Bid End date & time / Bid Opening date & time.

30. Forms of EMD and PBG



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Bidders can also submit the EMD with Banker's Cheque in favour of NEIGRIHMS EMD SECURITY DEPOSITS payable at MAWDIANGDIANG, SHILLONG-793018, MEGHALAYA. Bidder has to upload scanned copy / proof of the BC along with bid and has to ensure delivery of hardcopy to the Buyer within Bid End date & time / Bid Opening date & time.

31. Forms of EMD and PBG

Bidders can also submit the EMD with Payment online through RTGS / internet banking in Beneficiary name NEIGRIHMS EMD SECURITY DEPOSITS Account No. 30270200000027 IFSC Code BARB0MAWDIA Bank Name BANK OF BARODA Branch address MAWDIANGDIANG, SHILLONG-793018, MEGHALAYA. Bidder to indicate bid number and name of bidding entity in the transaction details field at the time of on-line transfer. Bidder has to upload scanned copy / proof of the Online Payment Transfer along with bid.

32. Forms of EMD and PBG

Successful Bidder can submit the Performance Security in the form of Account Payee Demand Draft also (besides PBG which is allowed as per GeM GTC). DD should be made in favour of NEIGRIHMS EMD SECURITY DEPOSITS payable at MAWDIANGDIANG, SHILLONG-793018, MEGHALAYA. After award of contract, Successful Bidder can upload scanned copy of the DD in place of PBG and has to ensure delivery of hard copy to the original DD to the Buyer within 15 days of award of contract.

33. Forms of EMD and PBG

Successful Bidder can submit the Performance Security in the form of Fixed Deposit Receipt also (besides PBG which is allowed as per GeM GTC). FDR should be made out or pledged in the name of NEIGRIHMS EMD SECURITY DEPOSITS A/C (Name of the Seller). The bank should certify on it that the deposit can be withdrawn only on the demand or with the sanction of the pledgee. For release of Security Deposit, the FDR will be released in favour of bidder by the Buyer after making endorsement on the back of the FDR duly signed and stamped along with covering letter. Successful Bidder has to upload scanned copy of the FDR document in place of PBG and has to ensure delivery of hard copy of Original FDR to the Buyer within 15 days of award of contract.

34. Forms of EMD and PBG

Successful Bidder can submit the Performance Security in the form of Payment online through RTGS / internet banking also (besides PBG which is allowed as per GeM GTC). On-line payment shall be in Beneficiary name NEIGRIHMS EMD SECURITY DEPOSITS Account No. 30270200000027 IFSC Code BARB0MAWDIA Bank Name BANK OF BARODA Branch address MAWDIANGDIANG, SHILLONG-793018, MEGHALAYA. Successful Bidder to indicate Contract number and name of Seller entity in the transaction details field at the time of on-line transfer. Bidder has to upload scanned copy / proof of the Online Payment Transfer in place of PBG within 15 days of award of contract.

( C ) 35. Additional Terms and conditions & Scope of Work for CMC

Tenderer/Vendors/contractor should note that the following terms and conditions will apply specifically in addition to the Rules and the Regulation as applicable to such provide services in the Government of India.

1. Comprehensive Annual Maintenance Contract must include Labour, spares & Preventive Maintenance of all the excluding of battery, Accessories/Consumables
2. The terms and conditions of the tender and the agreement executed will be binding on the vendor/contractor. This offer is being issued in accordance with the terms & conditions of NEIGRIHMS / Government of India and in the manner specified herein shall operate to create a specific contract between the vendor/contractor (with whom the contract referred to) on one part and NEIGRIHMS, Shillong, on the other part.
3. The required spares to be replace must be genuine and certified from the OEM.
4. Repairs to be undertaken should be within specified configuration and maintaining the integration on internal circuit of equipment, any deviation on configuration/ specification the repair will not be acceptable. After repairs, a certificate to the effect that the equipment is in working order and safe for patient care and non-hazardous for the handler shall be submitted by the CMC holder.
5. Tenderer/Vendors/contractor is responsible to provide electrical and patient safety certificate after major repair of equipment which are used for direct patient care.
6. The system must be checked & calibrated after every spare changes and detail service report must be submitted to the user & BME.
7. 2 nos of Periodic preventive maintenance is mandatory irrespective of unlimited service /breakdown calls.
8. Same /Similar Standby system must be provided by the bidder if the system needs to send to workshop for any major repair.
9. Receipt of this offer may be acknowledged and a copy duly signed/stamped by the authorized signatory should be submitted before finalization of the agreement.
10. The Performance security shall be denominated in any one of the forms namely Account Payee Demand Draft or Fixed Deposit Receipt drawn from any nationalized bank in India or Bank Guarantee issued by a nationalized bank in India, pledge in favor of Deputy Director, NEIGRIHMS, and Shillong-793018 for an amount equivalent to 3% of the total cost of annual CMC. The validity of the Fixed Deposit receipt or Bank Guarantee will be upto 2 months beyond CMC period.
11. It may also be noted that there should be no negligence in providing services of any type, if any, complaint is received the contract will be terminated with immediate effect.
12. There will be 98% uptime warranty during CMC period on 24 (hrs) X 7 (days) X 365 (days) basis, with penalty, to extend CMC period by double the downtime period. The vendor shall ensure optimum uptime of the system during CMC period, failing which the initiate shall initiate stern action, as deemed fit.
13. During Comprehensive Maintenance Contract period, the supplier shall visit at each consignee's site for preventive maintenance including testing and calibration as per the manufacturer's service/ technical/ operational manual.

*[Signature]*

*[Signature]*

Store & Procurement Officer  
NEIGRIHMS SHILLONG

- al. The supplier shall visit each consignee site as recommended in the manufacturer's manual, but at least once in 6 months commencing from the date of the successful completion of warranty period for preventive maintenance of the goods.
14. Processing of bill may be considered on yearly basis with satisfactory report from the user department. The AM C/CMC bills should be certified by the concerned Head of the Department/ In- Charge , BME and the respective DM S/MS.
  15. Software updates should be provided free of cost during CMC. The first service call by the team of service engineers should be within 7 days of issue of this order.
  16. Settlement of disputes - Director, NEIGRIHMS or his authorized representative shall be the final authority in all disputes and decision will be binding on all concerned.
  17. All other terms & conditions are as per award of contract mentioned in pre-page.
  18. Bidders are required to sign the CMC contract agreement within 15 (fifteen) days from the issue of the letter of award/supply order, failing which EMD/security deposit may be forfeited or Contract declared null and void.

**2.2. Buyer Added Bid Specific ATC:**


Buyer uploaded ATC document [Click here to view the file.](#)

Price Offered for Spares / Consumables | पूर्ण / उपभोग्य सामग्रियों के लिए प्रस्तावित मूल्य:

Price Offered for Spares / Consumables Document link | पूर्ण / उपभोग्य सामग्रियों के दस्तावेज़ लिंक के लिए प्रस्तावित मूल्य

Note: This is system generated file. No signature is required. Print out of this document is not valid for payment/ transaction purpose.

नोट: यह सिस्टम जनरेट फाइल है। कोई हस्ताक्षर की आवश्यकता नहीं है। इस दस्तावेज़ का प्रिंट आउट भुगतान/लेनदेन उद्देश्य के लिए मान्य नहीं है।

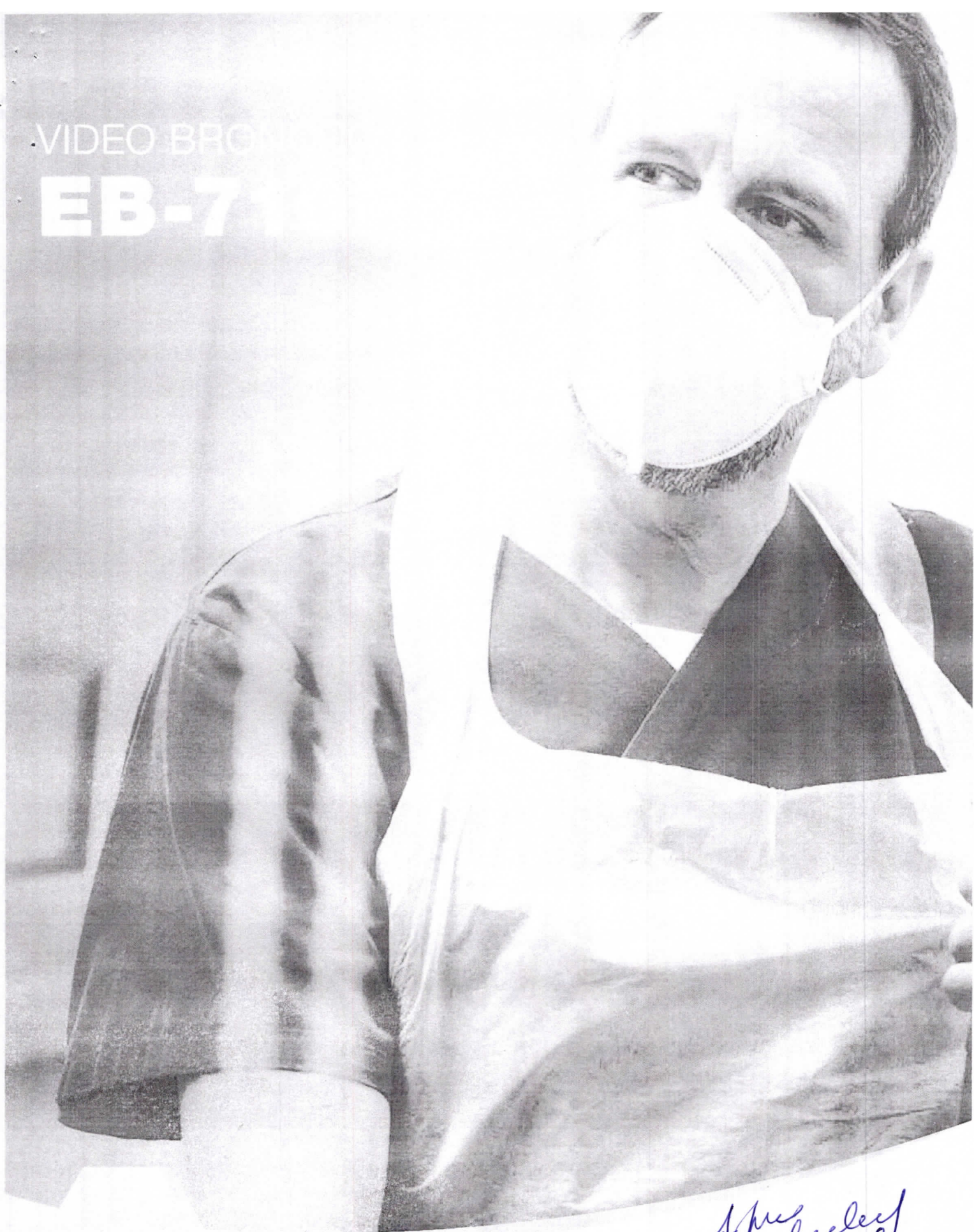


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NEIGRIHMS Shillong-18



VIDEO BROCHURE

EB-71



*film*

*Paul*

*Spec sheet*  
**FUJIFILM**  
Value from Innovation  
Store & Procurement Officer  
NEIGRIHMS Shillong-18  
*Supriya*

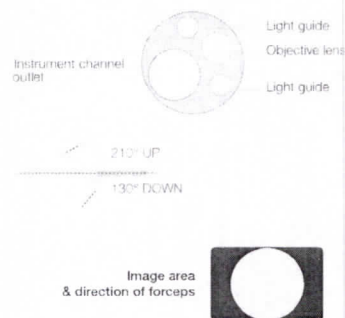
# ELUXEO VIDEO BRONCHOSCOPE Standard type



This slim standard video bronchoscope has a distal end diameter of 4.1 mm and a minimum instrument channel diameter of 2.0 mm. It is compatible with VP-7000 and EP-6000 processors. The One-step Connector can be connected to the light source in a single step without the need for additional cables. The EB-710P is compatible with low temperature Hydrogen Peroxide Gas Plasma sterilization.

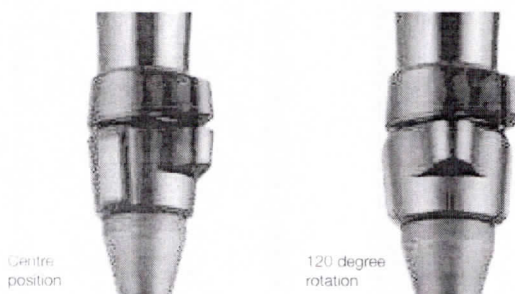


|  |                     |
|--|---------------------|
| Field of view                          | 120°                |
| Viewing direction                      | 0° (Forward)        |
| Observation range                      | 2 to 50 mm          |
| Bending capability                     | Up 210° / Down 130° |
| Distal end diameter                    | 4.1 mm              |
| Insertion tube diameter                | 4.1 mm              |
| Minimum diameter of instrument channel | 2.0 mm              |
| Working length                         | 600 mm              |
| Total length                           | 880 mm              |



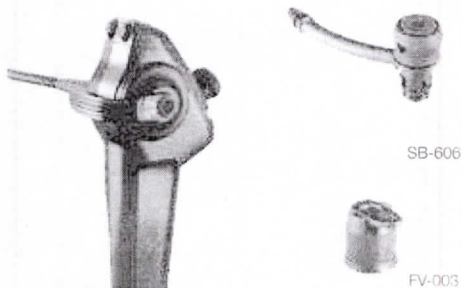
## Rotation function

The new rotation function enables 120 degree rotation of the insertion portion.



## Enhanced control portion with improved ergonomics

New control portion equipped with a wider grip, new suction valve, and four switches. The new SUC valve SB-606 allows easy holding in loading SUC tube. SB-606 & FV-003 are sterilized and single use.



reddot winner 2022



Illumination suitable for observation using variable LED light intensity.



Brilliant image transmission with reduced noise thanks to a CMOS-chip positioned directly in the tip.



Increased contrast in red colour leads to improved visibility of abnormalities, inflammation and delineation.



The combination of special light wavelengths results in improved contrast imaging for characterisation.



Easy to plug in with an integrated wireless power supply to provide high speed transmission of data.



Combine equipment displaying this logo to ensure that you view HDTV images on your monitor.

**FUJIFILM**

**FUJIFILM Europe GmbH**

Balcke-Dürr-Allee 6, 40882 Ratingen, Germany  
+49 2102 5364-0, [endoscopy\\_eu@fujifilm.com](mailto:endoscopy_eu@fujifilm.com)  
[www.fujifilm-endoscopy.com](http://www.fujifilm-endoscopy.com)

*Handwritten signatures and stamps:*  
Store & Procurement Officer  
NEIGHING SHONG-18  
Samar Kapor





U.S. FOOD & DRUG  
ADMINISTRATION

November 10, 2022

FUJIFILM Corporation  
% Kotei Aoki  
Senior Regulatory Affairs Specialist  
FUJIFILM Healthcare Americas Corporation  
81 Hartwell Avenue, Suite 300  
Lexington, Massachusetts 02421

Re: K220957

Trade/Device Name: FUJIFILM Endoscope Model EB-710P  
Regulation Number: 21 CFR 874.4680  
Regulation Name: Bronchoscope (flexible or rigid) and accessories  
Regulatory Class: Class II  
Product Code: EOQ  
Dated: October 13, 2022  
Received: October 13, 2022

Dear Kotei Aoki:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

U.S. Food & Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
2024-10-10

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NEIGHBORHOOD Shillong-18

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requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us/division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joyce C. Lin -S

for Shu-Chen Peng, Ph.D.

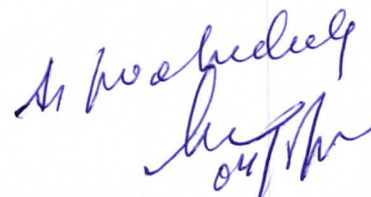
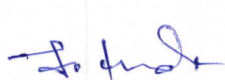
Assistant Director

DHT1B: Division of Dental and  
ENT Devices

OHT1: Office of Ophthalmic, Anesthesia,  
Respiratory, ENT and Dental Devices

Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure



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NEIGRIHMS Shillong-18

For Special Attention  
Sushant Kumar  
2022/11/18



## Indications for Use

510(k) Number (if known)  
K220957

Device Name  
FUJIFILM Endoscope Model EB-710P

### Indications for Use (Describe)

FUJIFILM Endoscope Model EB-71 OP is a bronchoscope intended for the observation, diagnosis and endoscopic treatment of the trachea and bronchus at medical facilities under the management of physicians.

Never use this product for any other purposes.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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NEIGRIHMS Shillong-18

## 510(k) Summary

FUJIFILM Corporation

FUJIFILM Endoscope Model EB-710P

Date: March 31, 2022

## Submitter's Information:

FUJIFILM Corporation  
798 MIYANODAI KAISEI-MACHI  
ASHIGARAKAMI-GUN, KANAGAWA  
258-8538 JAPAN

## Contact Person:

Kotei Aoki  
Senior Regulatory Affairs Specialist  
E-Mail: kotei.aoki@fujifilm.com  
Telephone: (765) 246-2931

## Identification of the Proposed Device:

|                         |                                  |
|-------------------------|----------------------------------|
| Device Name:            | FUJIFILM Endoscope Model EB-710P |
| Common Name:            | Bronchoscope                     |
| Product Code:           | EOQ                              |
| Device Class:           | Class 2                          |
| Regulation Number:      | 874.4680                         |
| Regulation Description: | Bronchoscope                     |
| Review Panel:           | Ear Nose & Throat                |

## Predicate Device:

- FUJIFILM Endoscope Model EB-580S (K183607)

## Reference Devices:

- FUJIFILM Endoscope Model EC-760S-V/L (K190649)
- OLYMPUS Endoscope Model BF-P190 (K201758)

## Intended Use / Indications for Use:

FUJIFILM Endoscope Model EB-710P is a bronchoscope intended for the observation, diagnosis and endoscopic treatment of the trachea and bronchus at medical facilities under the management of physicians.

Never use this product for any other purposes.

## Device Description:

FUJIFILM Endoscope Model EB-710P is comprised of three general sections: an insertion portion, a control portion, and a connector portion to the peripherals. The insertion portion is flexible and contains glass fiber bundles, several channels, and a complementary metal-oxide semiconductor (CMOS) image sensor in its distal end. The glass fiber bundles allow light to travel through the endoscope and emit light from the tip of the insertion portion to illuminate the body cavity. This provides enough light to the CMOS

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image sensor to capture an image and display it on the monitor. The channels in the insertion portion assist in delivering suction as well as endoscopic accessories. The control portion controls the angulation and rotation of the bending portion in the insertion portion. The connector portion consists of electronic components needed to operate the endoscope when connected to the video processor. The endoscopes are used in combination with FUJIFILM's video processors, light sources, and peripheral devices such as monitor, printer, foot switch, and cart.

### Comparison of Technological Characteristics:

The comparison is summarized in the tabular format in Tables below.

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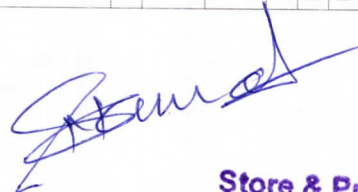
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~~James~~

Table 1

| Proposed Device<br>FUJIFILM Endoscope<br>Model EB-710P<br>(to be assigned) |            | Predicate Device<br>FUJIFILM Endoscope<br>Model EB-580S<br>(K183607)  | Reference Device 1<br>FUJIFILM Endoscope<br>Model EC-760S-V/L<br>(K190649)   | Reference Device 2<br>OLYMPUS Endoscope<br>Model BF-P190<br>(K201758) |
|--|------------|---|--|---|
| Indications for Use (IFU)  |            | The device is intended for the observation, diagnosis, and endoscopic treatment of trachea and bronchial tree.  |  |   |
| Viewing direction  |            | Forward / 0°  |  |   |
| Observation range  |            | 2mm - 50mm  |  | 2mm - 50mm  |
| Acceptance Criteria of Resolution  |            | At 2mm of working distance: 0.08mm of line pair on the square wave chart is readable.<br>At 50mm of working distance: 1.25mm of line pair on the square wave chart is readable. | At 4mm of working distance: 0.1mm of line pair on the square wave chart is readable.<br>At 100mm of working distance: 1.6mm of line pair on the square wave chart is readable. |   |
| Field of View  |            | 120°  |  |   |
| Bending capability   | Vertical   | Up 210° / Down 130°   |  |   |
|  | Horizontal | Right N/A / Left N/A  |  |   |
| Rotation capability (Insertion portion)                                    |            | Right: 120° / Left: 120°  | N/A  | Right: 120° / Left: 120°  |
| Image sensors  |            | CMOS  | CMOS   |   |
| Distal end diameter  |            | 4.1mm   | CCD  | 4.2mm   |
| Flexible portion diameter  |            | 4.1mm   | 5.3mm  | 4.1mm   |
| Maximum insertion diameter   |            | 4.9mm   | 5.1mm  |   |
| Forceps channel diameter   |            | 2.0mm   | 6.5mm  |   |
| Working length   |            | 600mm   | 2.2mm  | 2.0mm   |
| Total length   |            | 880mm   | 870mm  | 880mm   |
| Connector (communication)  |            | Scope Connector   | LG connector/Video connector   | Scope Connector   |


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| method)                                  | (optical communication)  | (electrical contact)  | (optical communication) |
|--|--|---|-------------------------|
| Connector power supply                   | Installed  | N/A   | Installed               |
| Connector CPU/Software                   | Suction Channel Brush (WB7025DC)<br>Cylinder/Inlet Brush (WB11003DV) |   |                         |
| Standard Accessories                     | Suction Valve (SB-607)   | Suction button (SB-500B/D)                                    |                         |
|  | Forceps Valve (FOV-BU1)  | Forceps Valve (FOV-DV7)                                       |                         |
|  | Cleaning Adapter (CA-616)  | Cleaning Adapter Kit (CA-500C)                                |                         |
| Optional Accessories                     | Ventilation Adapter (AD-7)   |   |                         |
|  | Air leak tester (LT-7F)  |   |                         |
|  | Suction Valve (SB-606)   | Suction Valve (SB-602)  |                         |
| Light Source/Video Processor             | Forceps Valve (FV-003)   |   |                         |
|  | BL-7000/VP-7000  | XL-4450/VP-4440HD<br>EPX-3500HD<br>BL-7000/VP-7000<br>EP-6000 | BL-7000/VP-7000         |
|  |  | Endoscopic Accessories  |                         |
| Peripherals                              | Electrosurgical Instruments  |   |                         |
| Control Portion<br>STERRAD Sterilization | New control portion  | G5 control portion  |                         |
|  | Yes  | No  |                         |

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**NEIGRIHMS Shillong-18**

### Performance Data:

Validation of the cleaning, disinfection, and sterilization instructions was performed in accordance with FDA's guidance, *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*, published March 17, 2015.

Biocompatibility of the proposed device was evaluated using the following consensus standards: ISO 10993-1:2018, ISO 10993-5:2009, and ISO 10993-10:2010. Biocompatibility testing was conducted in accordance with the FDA guidance, *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"*, issued September 4, 2020.

Software of the proposed device was evaluated in accordance with IEC 62304:2006 and the FDA guidance, *Guidance for the Content of Premarket Submission for Software Contained in Medical Devices*, issued May 11, 2005, and, *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*, issued October 2, 2014.

Electrical safety and EMC of the proposed device was evaluated using following standards: ANSI/AAMI ES 60601-1:2012, IEC 60601-1-2:2014, IEC 60601-1-6:2010/AMD1:2013, and IEC 60601-2-18:2009

Laser safety and photobiological safety of the proposed device was evaluated using the following standards: IEC 60825-1:2007 and IEC 62471:2006.

Endoscope specific testing was conducted according to ISO 8600-1: 2015

The proposed device met performance specifications in the following additional testing:

- |                      |                               |              |
|----------------------|-------------------------------|--------------|
| • Field of view      | • Working length              | • Resolution |
| • Bending capability | • Diameter of forceps channel | • LG output  |
| • Rate of suction    | • Viewing direction           |              |

Optical and color performance of the proposed device was evaluated. In all cases, the proposed device demonstrated substantial equivalence to the predicate device.

### Conclusions:

The proposed device FUJIFILM Endoscope Model EB-710P shares the same intended use and indications for use as, similar technological characteristics to, the same principles of operation as, and similar materials to the predicate device and the reference devices. The remaining differences in EB-710P, compared to the predicate device, have either 1) been cleared in the reference devices or 2) been evaluated for the biocompatibility, the electrical safety, the EMC testing, and the bench testing. The testing demonstrates that the proposed device remains as safe and effective as the predicate device and there is no new concern regarding the safety and effectiveness. FUJIFILM Endoscope Model EB-710P is substantially equivalent to the predicate device, FUJIFILM Endoscope Model EB-580S (K183607).

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*[Signature]*





Management Service

# CERTIFICATE

The Certification Body  
of TÜV SÜD Management Service GmbH  
certifies that

**FUJIFILM Corporation**  
26-30 Nishiazabu 2-Chome, Minato-Ku,  
Tokyo 106-8620 JAPAN

including the sites and scope of application  
see enclosure

has established and applies  
a Quality Management System.

An audit was performed, Order No. 73586643.

Proof has been furnished that the requirements  
according to

**ISO 9001:2015**

are fulfilled.

The certificate is valid from **2021-11-01** until **2024-10-31**.

Certificate Registration No.: **12 100 13904 TMS**.

*[Signature]*

*[Signature]* *[Signature]*  
Head of Certification Body  
Munich, 2021-10-20

Page 1 of 3

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**Store & Procurement Officer**  
**NEIGRIHMS Shillong-18**




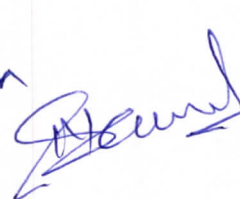
DAKKS  
Deutscher  
Akademischer  
Dienstleistungs-  
Kontrollrat



Management Service

Enclosure of Certificate Registration No.:  
12 100 13904 TMS

| Sites   | Scope of application   |
|---|--|
| <b>FUJIFILM Corporation</b><br>26-30 Nishiazabu 2-Chome, Minato-Ku,<br>Tokyo 106-8620 JAPAN                         | Site Representative  |
| <b>FUJIFILM Corporation</b><br>798, Miyanodai, Kaisei-Machi,<br>Ashigarakami-Gun,<br>Kanagawa 258-8538 JAPAN        | Design and Development of Digital Radiography and Accessories, Computed Radiography and Accessories, Imaging Plates for Computed Radiography, Digital Mammography and Accessories, Diagnostic X-Ray Equipment and Accessories, Workstations, Medical Endoscopes and Peripherals and Accessories, Ultrasonic Endoscopes and Peripherals and Accessories, Automatic Endoscope Reprocessor, Ultrasonic Diagnostic Imaging Equipment and Accessories, Medical Imager and Accessories, Cassette, Imaging Plates for Science Imaging Equipment, Science Imaging Equipment, Clinical Chemistry Analyzer, Densitometry Analyzer, Blood Collection Kit for Blood Test, Reagents and Related Products for In-Vitro Diagnostics; Categorized as Dry Chemistry and Immunoassay Tests. Quality Assurance of Film Processor. |
| <b>FUJIFILM Corporation</b><br>26-30 Nishiazabu 2-Chome, Minato-Ku,<br>Tokyo 106-8620 JAPAN                         | Design and Development,<br>Distribution of Workstations.   |
| <b>FUJIFILM SOFTWARE CO., LTD.</b><br>798, Miyanodai, Kaisei-Machi,<br>Ashigarakami-Gun,<br>Kanagawa 258-8538 JAPAN | Design and Development of Digital Radiography and Accessories, Computed Radiography and Accessories, Digital Mammography and Accessories, Diagnostic X-Ray Equipment and Accessories, Medical Endoscopes and Peripherals and Accessories, Ultrasonic Endoscopes and Peripherals and Accessories, Automatic Endoscope Reprocessor, Ultrasonic Diagnostic Imaging Equipment and Accessories, Medical Imager and Accessories, Clinical Chemistry Analyzer.  |

  
  
Head of Certification Body  
Munich, 2021-10-20

Page 2 of 3



DAkKS  
Deutsche  
Zertifizierungsstelle  
D-25142 01 00





Management Service

Enclosure of Certificate Registration No.:  
12 100 13904 TMS

| Sites   | Scope of application  |
|---|---|
| <b>FUJIFILM Corporation</b><br>MID TOWN WEST, 9-7-3, Akasaka,<br>Minato-Ku, Tokyo 107-0052 JAPAN  | Distribution of Digital Radiography and Accessories, Computed Radiography and Accessories, Imaging Plates for Computed Radiography, Digital Mammography and Accessories, Diagnostic X-Ray Equipment and Accessories, Medical Imager and Accessories, Cassette, Workstation, Ultrasonic Diagnostic Imaging Equipment and Accessories, Medical Endoscopes and Peripherals and Accessories, Ultrasonic Endoscopes and Peripherals and Accessories, Automatic Endoscope Reprocessor, Clinical Chemistry Analyzer, Densitometry Analyzer, Blood Collection Kit for Blood Test, Reagents and Related Products for In-Vitro Diagnostics, Categorized as Dry Chemistry and Immunoassay Tests. |
| <b>FUJIFILM SOFTWARE CO., LTD.</b><br>NOMURAFUDOSANSHINYOKOHAMA BLDG.<br>7F., 2-10-23, Shin-Yokohama, Kohoku-Ku,<br>Yokohama, Kanagawa 222-0033 JAPAN | Design and Development,<br>Distribution of Workstations.  |

*Store & Procurement Officer*  
*NEIGRIHMS Shillong-18*

Store & Procurement Officer  
NEIGRIHMS Shillong-18

*Paul Dahl*

Head of Certification Body  
Munich, 2021-10-20



DAKKS

Deutscher  
akkreditierungsdienst  
D 2511-147-11-00

No. G1 020011 0048 Rev. 01

**FUJIFILM Corporation**  
26-30, Nishiazabu 2-Chome  
Minato-Ku, Tokyo  
106-8620 JAPAN

|                        |  |
|------------------------|--|
| Product Category(ies): | Computed Radiography Console, Diagnostic X-ray Equipment, Digital Mammography System and related equipment, Software for Diagnostic Imaging Workstations, Ultrasound Diagnostic Imaging Equipment, Endoscopes for medical use and their related equipment and accessories, Ultrasound Endoscopes and their related equipment and accessories |
|------------------------|--|

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: JAQ235040080

Valid from: 2020-02-18

Valid until: 2024-05-26

Date: 2020-02-18

C.D.H.

Christoph Dicks

Head of Certification/Notified Body

for the

General

Life  
cheeky  
open

Store & Procurement Officer  
NEIGRAMS Shillong-18



No. G1 020011 0048 Rev. 01

Facility(ies):

FUJIFILM Corporation  
26-30, Nishiazabu 2-Chome, Minato-Ku, Tokyo,  
106-8620 JAPAN

FUJIFILM Corporation  
798, Miyanodai, Kaisei-Machi, Ashigarakami-Gun,  
Kanaqawa, 258-8538 JAPAN

-/-