



**ALL INDIA INSTITUTE OF MEDICAL SCIENCES**  
**Department of Pediatrics, Mother & Child Block**  
**ANSARI NAGAR, DELHI-110029**

Date 02-01-2025

**Subject: Proposal for procurement of MiroCam MC1200 Endoscopy Capsule, 170Deg FOV with Sensor Pad for Pediatric Gastroenterology Division at Department of Pediatrics, Mother & Child Block, AIIMS, New Delhi-110029 on PAC basis and invitation of comments/objections against such consumables if any, thereof.**

The Division of Neonatology at Department of Pediatrics, Mother & Child Block, AIIMS, New Delhi is in the process of procuring of **MiroCam MC1200 Endoscopy Capsule, 170Deg FOV with Sensor Pad** for Neonatal Intensive Care Unit at Department of Pediatrics at Mother & Child Block.

Therefore, this document is being uploaded for open information to all principal manufacturers or their authorized distributor with the intention to invite comments and/or objections with regards to the proprietary nature of the aforesaid product if any.

The comments/objections if any should be received in the office of the Stores Office, Room no. 817, 8<sup>th</sup> Floor, Department of Pediatrics, Mother & Child Block, AIIMS, Ansari Nagar, New Delhi - 110029 on or before **20/01/2025** up to 05.00 PM with contact details, failing which it will be presumed that no other bidder/ manufacturer/vendor is having any comments/objection against the proposition and the case will be decided purely on merit.

The matter pertains to the approval of the competent authority within the Department of Pediatrics at AIIMS.

O/IC Stores

Dept of Pediatrics

डॉ. बिस्वरोप चक्रवर्ती  
**Dr. BISWAROOP CHAKRABARTY**  
अपर आचार्य / Additional Professor  
7 बालिका प्रयोग / Child Neurology Division  
जलरोध चिकित्सा विभाग / Dept. of Pediatrics  
ज.आ.स., नई दिल्ली-29/AIIMS, New Delhi-29



# Emblica Bio Private Limited

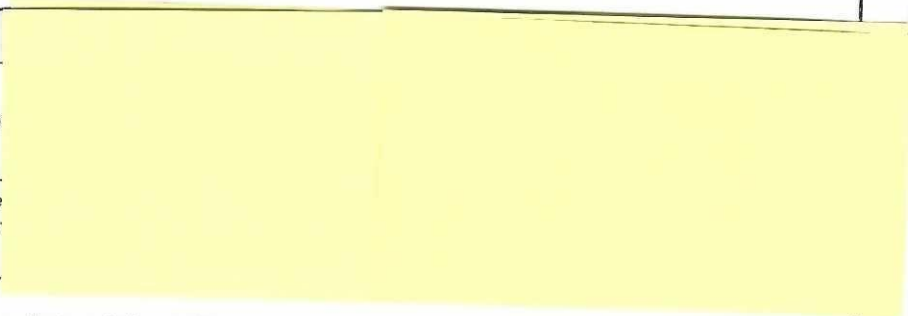
102, First Floor, DDA Building # 5  
 District Centre, Janakpuri  
 New Delhi-110058 India  
 Tel: +91 11 4172 9566, +91 97736 86295  
 Email: Connect@emblicabio.com

Customer Information		Our Ref#:	EMBL24-MiC/042
Department of Pediatric Gastroenterology		Date	November 27, 2024
All India Institute of Medical Sciences		Valid up to	March 31, 2025
Ansari Nagar		GSTIN	07AAGCE8708A1ZV
New Delhi-110029		MSME Regd#	UDYAM-DL-11-0029195
		PAN#	AAGCE8708A

Dear Sir/ Madam:

May we introduce ourselves as distribution partners for Intromedic Co Ltd, South Korea for its MiroCam Brand of Capsule Endoscopy System and its consumables/ spares. A letter of authorization is attached here for your files. For your MR1100 Capsule Endoscopy System, we are quoting the price of MC1200 Capsule which you may want to consider ordering

Sr.#	Part#	Description	HSN
1	MC1200	MiroCam MC1200 Endoscopy Capsule, 170Deg FOV with Sensor Pad	90181990
**		Tax (IGST, CGST, SGST) will be charged as applicable on the date prevailing rates. Currently it is being charged @ 12%. Should GST downwards, the same shall be applicable	



## PAYMENT TERMS : Within 30 days from the date of Supply

Beneficiary : EMBLICA BIO PRIVATE LIMITED

1 Bank : AXIS BANK LIMITED Address: Janakpuri-B Block, B1-1/ 503 Janakpuri, Janakpuri, New Delhi-110 058  
 CURRENT ACCOUNT# 922020011160662 ISFC Code: UTIB0001147  
 Payable at New Delhi

- 2 Delivery : Subject to availability of device and manpower. Pls allow atleast 2 working days
- 3 MC 1200 Endoscope will work only with MiroCam MR1100 or MR 2000 System only. Any commercially available Capsule other than manufactured by Intromedic Co Ltd ( MiroCam Brand) shall not be acceptable to MR1100 or MR2000 Endoscopy System.
- 4 The Capsule is consumable in nature, hence do not carry any warranty
- 5 Invoice payment delayed beyond 45 days shall attract interest @24% per annum compounded weekly. MSME Registration Certificate is attached which mandates payment to be made within 45 days
- 6 Items invoiced and dispatched shall not be taken back under any circumstances. We will not accept ant replacement of near Expiry/ Short Expiry or Expired stock
- 7 Disputes, if any shall be subject to Courts in Delhi
- 8 Any or all the terms stated here are deemed to have been accepted by you unless withdrawn in writing via Company email or thru a signed document by the Company.
- 9 Bank Charges if any due to Cheque return on account of any reason whatsoever or NEFT/RTGS failure due to any reason whatsoever shall be recovered from the Customer.

Mr. Raju Agarwal, Chief Business Officer  
 RAjagwal@emblicabio.com  
 Mobile# +91 98102 39840

10 Contact Nos  
 Mr. Mukesh Sharma  
 MSharma@emblicabio.com  
 Mobile# +91 92120 53839

for Emblica Bio Private Limited

*Ramesh*  
 /Dr. ROMAN MALIK  
 Additional Professor  
 Department of Gastroenterology & Hepatology  
 All India Institute of Medical Sciences, New Delhi-110029

**TO WHOMSOEVER IT MAY CONCERN**

This is to confirm that We, Intromedic Company Limited, Suite 1105, 1106, 41, Digital-ro 31-gil, Guro-gu, Seoul, 08375, Republic of Korea are Manufacturer and suppliers of MiroCam Brand of Capsule Endoscopes and Capsule Endoscopy system. We are selling through our Authorized Distributors in India, M/s Emblica Bio Private Limited, 102 First Floor, DDA Building # 5, District Centre, Janakpuri, New Delhi-110058 who supply the products and required technical support, consumable & spare parts.

- We hereby confirm that MC1200 Endoscopy Capsule is a consumable to be exclusive used on our MR1100 Capsule Endoscopy System.
- We hereby further confirm that MC1200 Endoscopy Capsule is not compatible with any other commercially available Capsule Endoscopy system EXCEPT MR1100 Capsule Endoscopy System.
- We hereby further confirm that MR1100 Capsule Endoscopy System shall not accept any commercially available Endoscopy Capsule in the world OTHER than MC1200



**IntroMedic Co., Ltd.**  
Suite 1105, 1106, 41, Digital-ro 31-gil,  
Guro-gu, Seoul, 08375, Republic of Korea

(Signature of Authorized Signatory)

For OEM

**Intromedic Company Limited**

Name: Cho Yong Seok

Designation: Chief Executive Officer

Date: - November 26, 2024



डॉ. रोहन मलिक / Dr. ROHAN MALIK  
अवर प्रोफेसर / Additional Professor  
Division of Gastroenterology & Hepatology  
सर्वजन विश्वविद्यालय / Department of Pediatrics  
एम्बिका बायो प्राइवेट लिमिटेड / EMBLICA BIO PRIVATE LIMITED, New Delhi-110058





Date: November 27, 2024

## Price Fall Clause Certificate

I/We, Emblica Bio Private Limited, the exclusive distribution partner of Intromedic Co Ltd Korea undertake that we have not offered to supply / supplied / are not supplying same MC1200 Endoscopy Capsule or similar products / systems or sub systems at a price lower than that offered to All India Institute of Medical Sciences in respect of any Organization/Ministry/Department of the Govt. of India or its Subsidiaries or other PSU or any other private organization during the currency of the contract and if it is found at any stage that same or similar product/systems or sub systems was supplied by the bidder to any Organization/Ministry/Department of the Govt. of India or its Subsidiaries or other PSU or any other private organization at a lower price during the currency of the contract, then that very price will be applicable to the present case and the difference in the cost would be refunded by the bidder to buyer, if the contract has already been concluded.

I/We also accept that:

1. I/We have to submit a copy of the last (latest) purchase order for the similar/ordered item(s) received from any Organization/Ministry/Department of the Govt. of India or its Subsidiaries or other PSU or any other private organization.
2. We will inform the purchaser of offer to supply/supply of the similar/ordered item(s) at a lower rate to any Organization/Ministry/Department of the Govt. of India or its Subsidiaries or other PSU or any other private organization during the currency of the contract.

Date: November 27, 2024



Authorized Signatory  
Name: Raju Agarwal  
Designation: Director

Seal of the Firm



डॉ. रोहन मालिक / Dr. ROHAN MALIK  
अपर प्रोफेसर / Additional Professor  
Division of Gastroenterology & Hepatology  
संस्कृत विश्वविद्यालय / Department of Pediatrics  
स.स. 110016, नई दिल्ली / New Delhi-110016

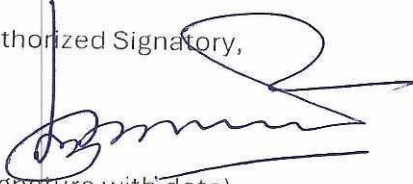
Date: November 27, 2024

## RATE REASONABILITY CERTIFICATE

I/We, Emblica Bio Private Limited, the exclusive distribution partner of Intromedic Co Ltd Korea certifies: -

- That the rates quoted for MC1200 Endoscopy Capsule vide our Quotation No. EMBL24-MiC/042 dated November 26, 2024 for Indian Rupees 32000.00 per qty plus applicable Taxes addressed to Department of Pediatrics', Gastroenterology, All India Institute of Medical Sciences, New Delhi-110029 are exclusively for supply to Government Hospitals/ ACADEMIC and RESEARCH Institutions and are not more than as charged to other Government /PSU's for same supplies made in recent past.
- That the quoted prices are the minimum and neither we have quoted the same item on lesser rates, than those being offered to Department of Pediatrics', Gastroenterology, All India Institute of Medical Sciences, New Delhi-110029, to any other customer for same supplies made in recent past, and nor we will do so till the validity of offer or execution of purchase order, whichever is later. If these rates are approved by the Department of Pediatrics', Gastroenterology, All India Institute of Medical Sciences, New Delhi-110029 and if at any stage the quoted rates are found higher than the rates applicable to supply to Government, then in such condition Department of Pediatrics', Gastroenterology, All India Institute of Medical Sciences, New Delhi-110029 will have the right to cancel the approved rates/Purchase order and to take legal action against the tenderer.

Authorized Signatory,



(Signature with date)

Name: Raju Agarwal

Designation: Director

Seal:



डॉ. रोहन मलिक / Dr. ROHAN MALIK  
अपर आचार्य / Additional Professor  
Division of Gastroenterology & Hepatology  
सर्वरोग चिकित्सा विभाग / Department of Pediatrics  
अशुभ काम नां दिल्ली / ALL INDIA - New Delhi



## AUTHORIZATION LETTER

Date: May 14, 2024

TO WHOM IT MAY CONCERN

In continuation to the Authorization Letter dated 21<sup>st</sup> April 2022, This is to confirm that We, **Intromedic Co Limited, Republic of Korea** who are world leading manufacturer and supplier of **MiroCam** brand of Capsule Endoscopes having factories at Suite 1105, 1106, 41, Digital-ro 31-gil, Guro-Gu, Seoul, Korea, 08375 have appointed Emblica Bio Private Limited, 102 First Floor, DDA Building # 5, District Centre, Janakpuri, New Delhi-110 058, India as our business & distribution partners for Republic of India with effect immediate effect for the following products

- MiroCam MC1200 Endoscope Capsules (Consumable)
- MiroCam MC1600 Endoscope Capsules (Consumable)
- MiroCam MC2000 Endoscope Capsules (Consumable)
- MiroCam MC4000 Endoscope Capsules (Consumable)
- MiroCam MR2000 Video Capsule Endoscopy System

We request our Customer in India to contact Emblica Bio to purchase the MiroCam Capsules and related services henceforth.

Emblica Bio Private Limited has adequately trained resources to provide the after sales services to you. You may please contact Emblica Bio Private Limited at connect@emblicabio.com, RAgarwal@emblicabio.com, Mobile# +91 97736 86295, +91 98102 39840

This authorization is valid for three years from the date of issue of this letter.

For Intromedic Co Ltd



**IntroMedic Co., Ltd.**  
Suite 1105, 1106, 41, Digital-ro 31-gil,  
Guro-gu, Seoul, 08375, Republic of Korea

(Signature of Authorized Signatory)

Name: Cho Yong Seok

Title: CEO



डॉ. रोहन मलिक / Dr. ROHAN MALHI  
Additional Professor  
Division of Gastroenterology & Hepatology  
गुरुकुल मेडिकल कालोनी / Department of Pediatrics  
New Delhi-110028, India

Self attested



**Central Drugs Standard Control Organisation**  
**Directorate General of Health Services**  
**Ministry of Health & Family Welfare**  
**(Medical Device & Diagnostic Division)**

FDA Bhawan, Kotla Road  
New Delhi-110002  
Phone No-011-23236965  
Fax: 23236973

File No. : HQ/MD/2023/000218

To,

M/s Emblica Bio Pvt. Ltd., Office No-102, First floor,  
Dda Building No-05, District Centre, Janakpuri, New  
Delhi-110058, West Delhi, Delhi (India) - 110058  
Telephone No.: 9810239840 FAX: 1141729566

Dated : 14-NOV-2023

Sub:- **Import Licence under the Medical Device Rules, 2017 thereunder- regarding.**  
Sir,

Import License No. IMP/MD/2023/001310 is hereby forwarded to you which is subjected to the following conditions:-

1. The provisions of Drugs and Cosmetics Act 1940 and Rules thereunder are in addition to and not derogation of any other law for the time being in force and as such the licence(s) issued under Drugs and Cosmetics Act and Rules will be in addition to and distinct from any licence(s) which may be necessary under the Import Trade Control Regulations made of the Government of India, Ministry of Commerce.
2. The import licence(s) mentioned in para (1) above will not accordingly to itself / themselves be sufficient authority for import of Medical Devices covered by that / those licence(s) if under the Import Trade Control Regulations of the Commerce Ministry separate license(s) are required for import of such Medical Devices.
3. Therefore, it is advised to obtain, where necessary licence(s) for import of Medical Devices in question under the Import Trade Control Regulations.
4. Any literature or packing accompanying the Medical Devices or any matter stated on the label should not contravene the provisions of the Drugs and Magic Remedies (Objectionable Advertisement) Act.
5. The products and premises covered under this licence(s) are subjected to inspection by drugs regulatory officials as & when required.

Yours faithfully

**RAJEEV SINGH**  
Licence Authority  
**RAGHUVANSHI**  
**HI**

Digitally signed by RAJEEV SINGH  
RAGHUVANSHI  
DN: c=IN, o=CENTRAL DRUGS STANDARD  
CONTROL ORGANIZATION, ou=RAJEEV SINGH  
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*Rover*  
Dr. ROHAN MALIK  
Additional Professor  
Division of Gastroenterology & Hepatology  
Department of Pediatrics  
www.Delhi.gov.in

*Segal*  
Emblica Bio Private Limited  
New Delhi



FORM MD-15

[See sub-rule (1) of rule 36]

Licence to Import Medical Device

Licence No. : IMP/MD/2023/001310

1. M/s Emblica Bio Pvt. Ltd., Office No-102, First floor, Dda Building No-05, District Centre, Janakpuri, New Delhi-110058 , West Delhi, Delhi (India) - 110058 Telephone No.: 9810239840 FAX: 1141729566 is hereby licenced to import the medical device(s) manufactured by overseas manufacturer having manufacturing site as specified below.

2. Details of overseas manufacturer and manufacturing site under this licence

S.No	Name and Address of Manufacturer	Name and Address of Manufacturing Site
1	Legal Manufacturing Site : M/s IntroMedic Co., Ltd., Suite 1105, 1106, 41, Digital-ro 31-gil, Guro-gu, Seoul, 08375, Korea, Country: South Korea Telephone No.: 8228019300 FAX: 8228019330 E-Mail : james@intromedic.com	Actual Manufacturing Site : M/s IntroMedic Co., Ltd., Suite 1105, 1106, 41, Digital-ro 31-gil, Guro-gu, Seoul, 08375, Korea, Country: South Korea Telephone No.: 8228019300 FAX: 8228019330 E-Mail : james@intromedic.com

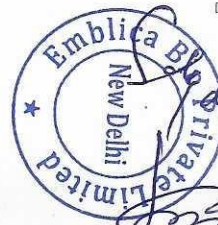
3. Details of medical device(s):

S.No	Medical Device Details
1	<p>1. Generic Name :MiroCam® Capsule Endoscope System (Along with components)</p> <p>2. Brand Name(if registered under the Trade Marks Act, 1999) :MiroCam®</p> <p>3. Class of Medical Device :Class B</p> <p>4. Shelf Life :12 months</p> <p>5. Sterile/Non-sterile:Non-Sterilized</p> <p>6. Intended Use :MiroCam® is intended for visualization of the small bowel mucosa as a tool in the detection of abnormalities of the small bowel. The device captures images of the small bowel with a wireless camera contained in a capsule. This device includes an ingestible capsule (containing light source, camera, transmitter, and battery), an electrode array, a receiving/recording unit, a data storage device, computer software to process the images (MiroView™ Software), and accessories.</p> <p>7. Material of Construction: capsule dome, plastic cage, gold plate and epoxy</p> <p>8. Dimension: 10.8x 30.1 mm</p> <p>9. Model No. :MC2000 - MC2000 series is intended for use in adults</p> <p>10. Accessory/Components :MiroCam® Capsule - N.A. Class B Dimension:N.A. Material:N.A. Shelflife: N.A. Non-Sterilized Intended Use:N.A. Model No:N.A.,MiroCam® Receiver - N.A. Class B Dimension:N.A. Material:N.A. Shelflife: N.A. Non-Sterilized Intended Use:N.A. Model No:N.A., MiroCam® Software - N.A. Class B Dimension:N.A. Material:N.A. Shelflife: N.A. Non-Sterilized Intended Use:N.A. Model No:N.A.</p>

RAJEEV SINGH  
RAGHUVANSHI  
HI

Digitally signed by RAJEEV SINGH RAGHUVANSHI  
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ou=RAJEEV SINGH RAGHUVANSHI,  
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Date: 2023.11.14 16:57:28 +05'30'

*Ram*  
डॉ. रोमन सलिक / Dr. Roman Salik  
अवर आयुर्वेद / Additional Professor  
Division of Gastroenterology  
प्राथमिक चिकित्सा / Department of  
Primary Care



2

1. Generic Name :MiroCam® Capsule Endoscope System (Along with components)
2. Brand Name(if registered under the Trade Marks Act, 1999) :MiroCam®
3. Class of Medical Device :Class B
4. Shelf Life :18 months
5. Sterile/Non-sterile:Non-Sterilized
6. Intended Use :MiroCam® is intended for visualization of the small bowel mucosa as a tool in the detection of abnormalities of the small bowel. The device captures images of the small bowel with a wireless camera contained in a capsule. This device includes an ingestible capsule (containing light source, camera, transmitter, and battery), an electrode array, a receiving/recording unit, a data storage device, computer software to process the images (MiroView™ Software), and accessories.
7. Material of Construction: capsule dome, plastic cage, gold plate and epoxy
8. Dimension: 10.8x 24.5 mm
9. Model No. :MC1200 - MC1200 series are intended for use in adults and children of two years of age . In a patient younger than 18
10. Accessory/Components :MiroCam® Capsule - N.A. Class B Dimension:N.A. Material:N.A. Shelflife: N.A. Non-Sterilized Intended Use:N.A. Model No:N.A.,MiroView™ Workstation - N.A. Class B Dimension:N.A. Material:N.A. Shelflife: N.A. Non-Sterilized Intended Use:N.A. Model No: MiroView™ Software

**RAJEEV SINGH**  
**RAGHUVANS**  
**HI**

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 DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ou=RAJEEV SINGH RAGHUVANSHI,  
 2.5.4.20=80c6276a23e4eafbe8a239774cdeb03c2769041015a96564fe67f54b765db1cb,  
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 Date: 2023.11.14 16:57:38 +05'30'



*Rm*  
 डॉ. रोहन मलिक / Dr. ROHAN MALI  
 अवर आचार्य / Additional Professor  
 Division of Gastroenterology & Hepatology  
 भारतीय चिकित्सा संस्थान / Department of Pediatrics  
 अ.स.प.स. (एन.ए.सी.) / All India Institute of Medical Sciences, New Delhi

4. The authorised agent M/s Emblica Bio Pvt. Ltd., Office No-102, First floor, Dda Building No-05, District Centre, Janakpuri, New Delhi-110058 , West Delhi, Delhi (India) - 110058 Telephone No.: 9810239840 FAX: 1141729566 will be responsible for the bussines activities of the overseas manufacturer, in India in all respects.

5. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

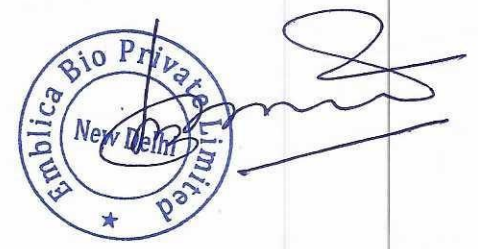
Place: New Delhi

RAJEEV SINGH  
RAGHUVANSHI  
HI

Digitally signed by RAJEEV SINGH RAGHUVANSHI  
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ou=RAJEEV SINGH RAGHUVANSHI - Central Licensing Authority, email=rajeev.singh@cdsco.gov.in, serialNumber=657F5E47D940985D8F03BDC902D0E1FE73CFA12A1A126EA94FA5701124A19013, cn=RAJEEV SINGH RAGHUVANSHI  
Date: 2023.11.14 16:57:44 +05'30'



*Self attested*



*R. Menon*  
अवर प्रोफेसर / Dr. KUNHAI MENON  
अवर आयुर्वेद / Additional Professor  
विभाग / Division of Gastroenterology & Hepatology  
आर.एम.एस. अस्पताल / R.M.S. Hospital  
नया दिल्ली / New Delhi



DNV

# MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:  
288528-2019-AQ-KOR-NA-PS

Initial certification date:  
06 March 2019

Valid:  
27 July 2023 – 26 July 2026

This is to certify that the management system of

## **IntroMedic Co., Ltd**

Suite 1105, 1106, 41, Digital-ro 31-gil, Guro-gu, Seoul, 08375, Republic of Korea

and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:

**ISO 13485:2016 / EN ISO 13485:2016**

This certificate is valid for the following scope:

**Design and Development, Production, Sales and Distribution of Capsule Endoscope Systems.**



*Ramesh*

Dr. ROHAN MALIK  
Additional Professor  
Department of Gastroenterology & Hepatology  
Department of Pediatrics

Place and date:  
Høvik, 07 June 2023

For the issuing office:  
DNV Product Assurance AS  
Veritasveien 1, 1363 Høvik, Norway



MSYS 018

*Cecilie Gudesen Torp*

**Cecilie Gudesen Torp**  
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid

ACCREDITED UNIT DNV Product Assurance AS, Veritasveien 1, 1363 Høvik, Norway - TEL: +47 67 57 99 00 www.dnv.com

ICP-4-5-15-ISO13485-11 rev2

**DNV**

Certificate no. 288528-2019-AQ-KOR-NA-PS  
Place and date: Høvik, 07 June 2023

## Appendix to Certificate

**IntroMedic Co., Ltd**

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
IntroMedic Co., Ltd	Suite 1105, 1106, 41, Digital-ro 31-gil, Guro-gu, Seoul, 08375, Republic of Korea	Production of Capsule Endoscope System
IntroMedic Co., Ltd (Branch Office)	F-RTEK 6F, 11-25, Simin-daero 327 beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do, 14055, Republic of Korea	Design and development, Sales and Distribution of Capsule Endoscope System

*Segallita*  


*Rohan*  
डॉ. रोहन मलिक / Dr. ROHAN MALI  
अवर प्रोफेसर / Additional Professor  
Division of Gastroenterology & Hepatology  
संस्कृत विश्वविद्यालय / Department of Pediatric  
नई दिल्ली / New Delhi, India