



Certificate of Compliance



Confirms that the Class II & 1s complies according to the directive Council Directive on Medical Devices 93/42/EEC as Amended 2007/47/EC.

Certificate No.: 2025070238

Manufacturer

Name : **FORCETO INDIA PRIVATE LIMITED**

Address : **PLOT NO 32 1ST FLOOR PATPARGANJ INDUSTRIAL AREA
DELHI 110092, INDIA**

Product : **PRODUCTS DETAILS AS PER APPENDIX – I OF VI**

The manufacturer's technical documentation as required for Medical Council according to the directive 93/42/EEC has been reviewed and found to comply with the requirements for Class II & 1s Council Directive on Medical Devices 93/42/EEC as Amended 2007/47/EC. Any significant changes in the design or construction of the product, not agreed upon by us, this declaration will lose its validity.

This certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type-examination procedures, if requested.
2. The certificate remains valid until the manufacturing conditions or the quality systems are changed.
3. The certificate validity is conditioned by positive results or surveillance audits.
4. The CE mark as shown above can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of conformity and compliance with all relevant EC Directives. The statement is based on a single evaluation of one sample of above mentioned product. It does not imply an assessment of the whole production.

Validity of this certificate can be verified at www.eurocertverify.com

Date of Certification 02nd July 2025

1st Surveillance Audit Due 01st July 2026

2nd Surveillance Audit Due 01st July 2027

Certificate Expiry (subject to the company maintaining its system to the required standard) 01st July 2028

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Company No. 11956886



Certificate of Compliance

Appendix-I

Appendix to Certificate no.:- 2025070238
Applicant : FORCEETO INDIA PRIVATE LIMITED
Products: PLOT NO 32 1ST FLOOR PATPARGANJ INDUSTRIAL AREA
DELHI 110092, INDIA



This certificate referred to above covers the following products like:

Product Name :

Appendix-I	
Product Group – 1 – LED Light Source	Type of Model/ Variants
Product	LED Light Source 100 Watt 7" Display
LED / Xenon Light Source	LED Light Source 100 Watt 5" Display
	Portable LED Light Source .50watt
	LED Handle Light Battery Operated
	Xenon Light Source
Product Group – 2 – Reusable Surgical Instruments (Non-sterile)	
	Trocars
	Safety Obturators for Trocar
	Pencil Safety Obturator 10mm
	Reduction Sleeve
	REDUCERS
	Washers
	Graspers
	Grasping Forceps
	Cholangiography Forcep
	Satensky Forcep with ring Handle
	Dissectors
	Scissors
	Clamps
	Needle Holders
	Bipolar Grasper
	Bipolar Dissector
	Bipolar Cutter
	Bipolar Scissors
	Dissecting & Grasping Forceps
	Clip Applicators
	hemlock clip applicator
	Knot Pusher
	Port Closure Needle
	Fan- Retractor
	Snake Retractor
	Bull-Dog applicator
	Suction and Irrigation Cannulas
	Nathanson Retractor
	Palpation Probe
	S-Shape Retractor
	Skin staple remover
	Insufflation Needles
	Ring applicator for Tubal-ligation
	Myoma fixation device,
	High Frequency needle for P.C.O.D.,
	Aspiration Needle
	CCL Extractor
	FLEXIBLE ELECTRODE (Bugbee)
	Vaginal Tube
	Marwah Manipulator
	Sukhedia Manipulator
	Mangeshkar Type Manipulator complete set

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Certificate of Compliance

Appendix-II

Appendix to Certificate no.:- 2025070238
 Applicant : **FORCETO INDIA PRIVATE LIMITED**
 Products: **PLOT NO 32 1ST FLOOR PATPARGANJ INDUSTRIAL AREA
 DELHI 110092, INDIA**



This certificate referred to above covers the following products like:

Product Group – 3 – Camera & Telescope Camera & Telescope	Telescope 2.9 mm, 4 mm, 5 mm & 10 mm Sinoscopes 4 mm, 2.7 mm Single CCD Camera without Recording Single CCD Camera with Recording Single Chip HD Camera Three CCD Camera High Definition Three Chip Camera without Recording High Definition Three Chip Camera with Recording High Definition C-MOS Camera with Recording Single C- Mos Camera Three C- Mos Camera
Product Group – 4 – O. T. Lights And Table O. T. Lights And Table	FULLY ELECTRIC TABLE Remote With Surgeon Pane General Purpose Manually Operated Operation Tables Electro Hydraulic Operating Tables Electro Mechanical Labour Tables Electro Mechanical Operating Tables Hydraulic Operating Table OPHTHALMIC TABLE; GYNE ELECTRIC; GYNE HYDRAULIC; SEMI ELECTRIC ONLY UP DOWN BY REMOTE; HYDRAULIC TABLE 304ss HYDRAULIC CARM 304SS Medical Examination Light, AC Powered or Battery Ceiling Twin Light 19" +19" Dia Dome Halogen Ceiling Light 4 Reflector, Mobile Light 4, Reflector Halogen Spring Balance Major Ceiling O.T. Lamp 4+7 Reflector Halogen Ceiling Suspended Shadow Less Lamp 4 Reflector Shadow Less O.T. Light Shadow Less Mobile Operation Lamps Counter Weight Balance 19" C Size 20" -4 Reflector Optional - Plan / Halogen Bulb Operation Lamp Plain Optional Size 12", 14", 16" Led Head Light Led Head Light with HD Camera
Product Group – 5- HYSTEROSCOPE HYSTEROSCOPE	Hysteroscopes 2.9mm or 4mm 2.9mm Hysteroscope and operative sheath is integrated as one piece Diagnostic Sheaths for Hysteroscopes 2.9mm or 4mm Continuous Flow Diagnostic Sheaths Hysteroscopes 2.9mm or 4mm Hysteroscopy Operating sheath for Hysteroscopes 2.9mm or 4mm Semi rigid Grasping Forceps for Hysteroscopes 2.9mm or 4mm Semi rigid Biopsy Forceps for Hysteroscopes 2.9mm or 4mm Semi rigid Scissors for Hysteroscopes 2.9mm or 4mm

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Certificate of Compliance

Appendix-III

Appendix to Certificate no.:-

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Applicant :

FORCETO INDIA PRIVATE LIMITED

Products:

PLOT NO 32 1ST FLOOR PATPARGANJ INDUSTRIAL AREA
DELHI 110092, INDIA



This certificate referred to above covers the following products like:

Product Group – 6 Tourniquet, Pneumatic	
Tourniquet Pneumatic	Tourniquet Pneumatic Single Channel with standard Accessories :- TOURNIQUIT CUFF, Silicone Tubing
	Tourniquet Pneumatic Dual Channel with standard Accessories :- TOURNIQUIT CUFF, Silicone Tubing
Product Group 7 – Insufflator	
Insufflator	Tubing/Tubing With Filter, Insufflation, Laparoscopic - Insufflator
	Insufflator 30 L/Min (Touch Screen),
	Insufflator 40 L/Min
	Insufflator, 30 L/Min, Insufflator 30 L/Min With Heating; Insufflator 40 L/Min (Touch Screen) With Heating,
	Insufflator 50 L/Min;
	Insufflator 40 L/Min With Heating,
	Insufflator 40 L/Min (Touch Screen) ;
	Insufflator 50 L/Min (Touch Screen),
	Insufflator 50 L/Min (Touch Screen) With Heating ;
	Insufflator 50 L/Min With Heating
Product Group 8 – Colposcope	
Colposcope	Colposcope Digital , HD Colposcope
Product Group 9 – Laryngoscope	
Laryngoscope	Laryngoscope, Non-Rigid - Fibre Optic ; Flexible Laryngoscope; Flexible Laryngoscope, Video
Product Group 10- ENT	

ENT	Rigid Bronchoscopy Set
	Rigid Laryngoscopy Set
	LED Headlights with HD Camera
	Endoscopes
	Sinuscopy Hand Instruments
	Septoplasty Set,
	Mastoidectomy instruments Set
	Rhinoplasty Instruments Set,
	Micro Laryngeal Instruments Set
	Tonsillectomy and Adenoidectomy Instruments Set,
	Tracheostomy Instruments Set,
	Tympanoplasty And Stapedectomy Set,
	Direct Laryngoscopy Set,
	Ear Microsurgery Set,
	Functional Endoscopic Sinus Surgery (FESS) Set,
	Major Nasal Set,
	Mastoid Surgery Set)

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Appendix-IV



Appendix to Certificate no.:-

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Applicant :

FORCETO INDIA PRIVATE LIMITED

Products:

PLOT NO 32 1ST FLOOR PATPARGANJ INDUSTRIAL AREA
DELHI 110092, INDIA



This certificate referred to above covers the following products like:

Product Group 11- General Surgical Instruments	Open Surgery Instruments
	Laparotomy set,
	General surgery set,
	C-section set,
	Ortho sets,
	Gynae set,
	Appendectomy set,
	Dressing Set,
	D&C Set,
	Delivery set,
	General Surgery Major set,
	Hysterectomy set,
	Instruments set Minor surgery,
	Instrument set postmortem,
	Instruments set VVF,
	GENERAL A.V FISTULA SET
	GENERAL DEEP RECTUM SURGERY SET
	GENERAL HERNIA & APPENDIX SET
	GENERAL THYROIDECTOMY SET
	GENERAL VATS SURGERY SET
	GYNEA L.S.C.S SET
	GYNEA VAGINAL HYSTERECTOMY SET
	GYNEA ABDOMINAL HYSTERECTOMY SET
	GYNEA H.S.G. SET
	GYNEA COLPOSCOPY SET
	GYNEA IUCD SET
	GYNEA PV SET
	Pediatric set,
	Transvaginal hysterectomy set,
	Neuro surgery set,
	Cardiac surgery set,
	Kidney Transplant Set
	Micro Surgery Instrument Set,
	ORTHO ACL SET
	ORTHO GENERAL SET
	Dental & Maxillofacial Surgery Instruments,
General Surgical Instruments	
Product Group 12- Paediatric Surgery	Pediatric Urology Instruments
	Pediatric HD Uretero
	Pediatric Laparoscopy Instruments
	Trocars and accessories
	Suction and Irrigation Cannulas
	Graspers, Dissectors & Scissors, Ø 3 mm & Ø 5 mm
	Claw Forceps
	Endo – Retractors
	Needle holders 3.0 mm and 5.0 mm diameter
Paediatric Surgery	
Product Group 13- Arthroscopy	Shaver System
Arthroscopy	Arthroscopy Pump
	Arthroscope and Sheath
	Arthroscopy Instruments
	Max-Line Arthroscopy Instruments
	Monopolar Arthroscopy Electrodes with Handle
	Monopolar Arthroscopy Electrodes for 4 mm and 2.36 Pen
	Bipolar Arthroscopy Electrodes for use in SALINE SOLUTION

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Certificate of Compliance

Appendix-V

Appendix to Certificate no.:- 2025070238

Applicant :

FORCETO INDIA PRIVATE LIMITED

Products:

**PLOT NO 32 1ST FLOOR PATPARGANJ INDUSTRIAL AREA
DELHI 110092, INDIA**



This certificate referred to above covers the following products like:

Product Group 14- Endoscopy Units	
Endoscopy Units	High Definition Monitors
	Suction & Irrigations Machine
	Irrigation Machine
	Pneumatic Lithotripter
	LED Headlights
	LED Headlights with HD Camera
	Ultrasonic Cleaning Machine
	Vacuum Delivery System Machine with Accessories
	Laparoscopy Trolley
Product Group 15- Urology	
Urology	Cystoscopes Ø 4.0 mm and 2.9 mm
	Cystoscope - Urethroscope Sheaths
	Working Elements with Albarran Deflector
	Laser Working Element
	Visual Obturators for Cystoscopes- Urethroscopes
	Optical Instruments
	Flexible Instruments for Urology
	Resectoscope and Accessories
	Resectoscope Sheaths
	Urethrotome and Accessories
	Nephroscope
	Nephroscopy Instruments
	HD Uretero – Renoscope
	Resectoscope Set 26Fr.
	Resectoscope Set 22Fr.
	Resectoscope Set 18.5Fr.
	Mini-Nephroscope (Mini-Perc)
	Laser Resectoscope Set
Other Product Category	PPE Kit, Surgical Gown, Gloves
Product Group 16- ICU BED ELECTRIC	
	ICU BED ELECTRIC
	Manual Hospital Bed
	Electro Hydraulic Bed
	ICU BED SEMI ELECTRIC
	SEMI FOWLER BED ELECTRIC
	PAEDIATRIC BED ELECTRIC
	ATTENDANT BED CUM CHAIR (STD.) ELECTRIC
	MATTRESS FOR HOSPITAL BED (32/40 DENSITY)
	Wheel Chair
	EMERGENCY STRETCHER TROLLEY, Patient Transfer Trolley, Stretcher Trolley

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Appendix-VI

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Products:

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This certificate referred to above covers the following products like:

Product Group 17- OTHER PRODUCTS	
BOTTLE, COLLECTION, VACUUM	Electrical & Mannual Suction,
	High Vacuum Fibre body,
	Portable Suction;
	Suction System Portable, Electrical / Pneumatic
	High Vacuum for Battery (Big),
	High Vacuum for Battery & Mannual;
	High Vacuum plus,
	High Vacuum plus High Capacity,
	High Vacuum MS;
	High Vacuum SS,
	High Vacuum Battery operated,
	High Vacuum for Gynae;
	Mobile Suction,
	High Vacuum Suction Rack Version
	High Vacuum for Lyposuction
UNIT, EXAMINING/ TREATMENT, ENT	Compressor,
	Warmer for Instrument ;
	Doctor Stool with adjustable backrest & Height, Suction Pump;
	ENT Examination Workstation Medium,
	ENT Examination Workstation Large;
	ENT Examination Workstation Small;
	Patient Examination & Treatment Chair
Helmet, Surgical	Helmet, Surgical
Laparoscopes	Laparoscope 10mm / 5 mm 0 Degree,
	Laparoscope 10mm / 5 mm 30 Degree,
	Laparoscope 10mm / 5 mm 45 Degree,
	Laparoscope 10mm 30 Degree for Bariatric Surgery,
	Laparoscope 10mm 45 Degree for Bariatric Surgery

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