



# 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.:** 2023041737

## Manufacturer

Name : MAHIKA MEDICAL PVT. LTD.

Address : OFFICE: E-117, PREET VIHAR, DELHI - 110 092 (INDIA)  
OFFICE: B-3/14, PREET VIHAR COMPLEX, DELHI - 110 092 (INDIA)  
FACTORY:- 51, PATPARGANJ INDUSTRIAL AREA, DELHI - 110 092 (INDIA)

Product : PRODUCTS DETAILS AS PER APPENDIX – I OF 10

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](http://www.eurocertverify.com)

Date of Certification	17 <sup>th</sup> April 2023
1 <sup>st</sup> Surveillance Audit Due	16 <sup>th</sup> April 2024
2 <sup>nd</sup> Surveillance Audit Due	16 <sup>th</sup> April 2025
Certificate Expiry (subject to the company maintaining its system to the required standard)	16 <sup>th</sup> April 2026

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Company No. 11956886



## Certificate of Compliance

## Appendix-I

Appendix to Certificate no.:- 2023041737  
Applicant : MAHIKA MEDICAL PVT. LTD.  
Products: OFFICE: E-117, PREET VIHAR, DELHI - 110092 (INDIA)  
OFFICE: B-3/14, PREET VIHAR COMPLEX, DELHI-110092 INDIA  
FACTORY:- 51, PATPARGANJ INDUSTRIAL AREA, DELHI - 110 092 (INDIA)



This certificate referred to above covers the following products like:

### Product Name :

- **MEDICAL APPARELS AND DISPOSABLES**
- Scrub Suits
- Patient Gown
- Hospital Bedding
- Bed Sheets
- Pillow Covers
- Pillows
- Patient Dress
- Surgeon OT Dress
- Surgeon Gown
- Surgeon Cap
- Surgeon Mask
- Reinforced Gown
- Doctor Coat
- Nurse Coat
- Drape
- Cut Sheet
- OT Towel
- Draw Sheet
- Table Sheet
- Abdominal Sheet
- Angiography Cut Sheet
- Reinforced Double Layer Drape
- Eye Sheet
- Mortuary Bag
- Nurse Uniform
- Housekeeping Uniform
- Hospital Blanket
- Hospital Curtain
- Cubicle Curtain
- Side Screen Curtain
- Door Curtain
- Couch Roll
- Wipes
- Medical Aprons
- Hospital Linen
- 2 Ply Face Mask (Loop)
- 2 Ply Face Mask (Tie)
- 3 Ply Face Mask (Loop)
- 3 Ply Face Mask (Tie)
- Surgeon Cap
- Bouffant Cap
- Surgeon Hood Cap
- Latex Powdered Gloves
- Latex Powder Free Gloves
- Vinyl Powdered Gloves
- Latex Surgical Gloves
- PE Poly Shoe Cover
- PE Anti Static Shoe Cover
- Non Woven Shoe Cover
- Non Woven Anti Static Shoe Cover
- Apron PE (HM)
- Apron SMS (Non woven)
- Gown Patient (PP spun bond)
- Gown Surgeon/Doctor (SMS)



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## Certificate of Compliance

## Appendix-II

Appendix to Certificate no.:- 2023041737  
Applicant : MAHIKA MEDICAL PVT. LTD.  
Products: OFFICE: E-117, PREET VIHAR, DELHI - 110092 (INDIA)  
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FACTORY:- 51, PATPARGANJ INDUSTRIAL AREA, DELHI - 110 092 (INDIA)



This certificate referred to above covers the following products like:

- Bed Sheet (PP spun bond)
- Bed Sheet (pp spun bond coated)
- Bed Sheet (SMS)
- Drape Sheet
- Underpad
- Mackintosh Sheet
- Tongue Depressor
- **FOGGER AND FUMIGATOR**
  - Fogger Machine Stainless Steel
  - Fogger Machine Plastic
  - Fumigator
  - Fogger Timer
  - Fogger Motor
  - Fogger Rotating Table
  - Fumigator Timer
- **Resuscitators, Anaesthesia Equipment and Accessories**
  - Silicone Resuscitator with Pop-off Valve (Adult, Child, Infant)
  - Black Rubber Resuscitator Autoclavable (Adult, Child, Infant)
  - Black Rubber Resuscitator Non- Autoclavable (Adult, Child, Infant)
  - Silicone Face Mask (Sizes 00, 0, 1, 2, 3, 4, 5)
  - Black Rubber Super Face Mask (Sizes 00, 0, 1, 2, 3, 4, 5)
  - Silicone Rendell Baker Face Mask (Sizes 00, 0, 1, 2, 3, 4, 5)
  - Anaesthesia (Antistatic) Face Mask (Sizes 00, 0, 1, 2, 3, 4, 5)
  - Anaesthesia Face Mask Transparent (Aircushion Face Mask with Valve) (Sizes 00, 0, 1, 2, 3, 4, 5)
  - Oxygen Mask with Reservoir Bag (Adult, Child, Infant)
  - Oxygen Mask (Adult, Child, Infant)
  - Nebulizer Mask (Adult, Child, Infant)
  - Venturi Mask with 6 Diluters
  - Venturi Mask with 1 Diluters
  - Oxygen Nasal Cannula (Adult, Child, Infant)
  - Oxygen Recovery Kit (Adult, Child, Infant)
  - Nebulizer T Piece
  - CPR Mask Mouth to Mouth (Adult, Child, Infant)
  - Pocket CPR Mask Disposable (Adult, Child, Infant)
  - Rebreathing Bag (Green) (0.5 to 6 Ltr.)
  - Rebreathing Bag (Black) (0.5 to 6 Ltr.)
  - Bain Circuit
  - Bain Circuit with APL Valve
  - Bain Circuit
  - Mapleson "F" System (Bain Circuit)
  - Paediatric Jackson Rees' System
  - Magill Circuit for Anaesthesia Machine Reusable with Mask
  - Anaesthesia Magill Circuit
  - Close Circuit
  - Coaxial Respiration Circuit
  - Ventilator Circuit Plain (Adult, Child, Infant)
  - Ventilator Circuit with Double Water Trap (Adult, Child, Infant)
  - Ventilator Circuit with Double Water Trap Adult with HME Filter, Catheter Mount & Mask
  - Ventilator Circuit with Single Water Trap (Adult, Child, Infant)
  - Ventilator Circuit with Double Water Trap & Proximal Line (Adult, Child, Infant)
  - Ventilator Circuit Single Limb with Proximal Line
  - Silicone Ventilator Circuit with Double Water Trap with Catheter Mount (Adult, Child, Infant)
  - Silicone Ventilator Circuit with Double Water Trap (Adult, Child, Infant)
  - Anaesthesia Breathing Circuit (Adult, Child, Infant)
  - Ventilator Circuit Expandable
  - Expandable Circuit with HME Filter & Catheter Mount
  - HME Filter (Adult, Child, Infant)
  - Bacteria Filter

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## Certificate of Compliance

## Appendix-III

Appendix to Certificate no.:-

2023041737T

Applicant :

MAHIKA MEDICAL PVT. LTD.

Products:

OFFICE: E-117, PREET VIHAR, DELHI - 110092 (INDIA)

OFFICE: B-3/14, PREET VIHAR COMPLEX, DELHI-110092 INDIA

FACTORY:- 51, PATPARGANJ INDUSTRIAL AREA, DELHI - 110 092 (INDIA)



This certificate referred to above covers the following products like:

- PFT Filter
- E.T. Tube Holder
- Humidifier Chamber Automatically Refills
- Catheter Mount Swivel Connector 15/22 mm
- Expendable Catheter Mount Swivel Connector 15/22 mm
- Silicone Catheter Mount Swivel Connector 15/22 mm
- Antistatic Corrugated Tube (42 inch, 16 inch, 12 inch)
- Antistatic Corrugated Tube
- Silicone Resuscitator without Pop-off Valve (Adult, Child, Infant)
- Smooth Bore Tubing Disposable P.V.C. Length: 1.5 Mtr Connector Size: 22 mm
- Manual Suction
- Cardio Stethoscope
- Stainless Steel Stethoscope
- Pediatric Stethoscope
- Stethoscope Spare Parts
  
- PVC Laryngeal Mask Airway (Size 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6)
- Silicone Laryngeal Mask Airway (Single Use) (Size 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6)
- Silicone Laryngeal Mask Airway (Reusable) (Size 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6)
- Bougie
- Intubation Kit
- Laryngoscope with 3 Blade (LED Light) & Handle (Adult and Child)
- Laryngoscope with 4 Blade (LED Light) & Handle (Adult and Child)
- Laryngoscope with 2 Blade (LED Light) & Handle (Adult and Child)
- Conventional Macintosh (White LED Light) Blades (Size 000, 00, 0, 1, 2, 3, 4, 5)
- Conventional Miller (White LED Light) Blades (Size 000, 00, 0, 1, 2, 3, 4, 5)
- Fiber Optic Laryngoscope with 4 Blades & Box (White LED Light) (Adult and Child)
- Fiber Optic Laryngoscope with 2 Blades & Box (White LED Light) (Adult and Child)
- Fiber Optic Macintosh Blades (Size 000, 00, 0, 1, 2, 3, 4, 5)
- Fiber Optic Miller Blades (Size 000, 00, 0, 1, 2, 3, 4, 5)
- Conventional Flexitip (Mc coy or Trupty) Blade (White LED Light) (Size 000, 00, 0, 1, 2, 3, 4, 5)
- Fiber Optic Flexitip (Mc coy or Trupty) Blade (Size 000, 00, 0, 1, 2, 3, 4, 5)
- Silicone (Ventouse) Cup Plain with Metal Nozzle
- Silicone (Ventouse) Cup with Release Valve
- Foot Suction
- Humidifier Bottle
- Yankauer Suction Set
- Oxygen Hood (Small, Medium, Large)
- Vacuum Extractor Bird Type with Three SS Cup
- Vacuum Extractor Malmstrom Type with Three SS Cup
- Vacuum Metal Cup with Rubber Tube
- Vacuum Metal Cup with Silicone Tube
- Guedel Airway (Single Use) (Size 000, 00, 0, 1, 2, 3, 4, 5)
- Guedel Airways (Reusable) (Size 000, 00, 0, 1, 2, 3, 4, 5)
- Guedel Airways (Plastic Box Packing)
- Nasopharyngeal Airway
- Silicone Head Harness
- CPAP Full Face Mask (Small, Medium, Large)
- Nasal Mask (Small, Medium, Large)
- Head Strap for CPAP Mask
- CPAP Mask Tube Length: 1.8 Mtr. & Connector Size: 22 mm Disposable
- Smooth Bore Tubing Disposable P.V.C. Length: 1.5 Mtr Connector Size: 22 mm
- Teeth Opener (Mouth Opener)
- Three Ball Lung Exerciser
- Single Ball Lung Exerciser
- Silicone Ring Pessary
- Stylet (Small, Medium, Large)

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## Certificate of Compliance

## Appendix-IV

Appendix to Certificate no.:-

2023041737

Applicant :

MAHIKA MEDICAL PVT. LTD.

Products:

OFFICE: E-117, PREET VIHAR, DELHI - 110092 (INDIA)  
OFFICE: B-3/14, PREET VIHAR COMPLEX, DELHI-110092 INDIA  
FACTORY:- 51, PATPARGANJ INDUSTRIAL AREA, DELHI - 110 092 (INDIA)



This certificate referred to above covers the following products like:

- Resuscitation Kit (Adult, Child, Infant)
- Test Lung
- Flow Meter with Humidifier Bottle (PC Bottle)
- BOC Flow Meter
- Flow Meter
- Single Stage Regulator with Tube
- Double Stage Regulator
- Regulator
- Regulator with Flow Meter
- Disposable Electrosurgical Pencil
- Manual Scution
  
- Pop-off Valve for Resuscitator (Adult, Child, Infant)
- Non Pop-off Valve for Resuscitator
- Reservoir Bag with Valve
- Oxygen Tube
- Silicone Rebreathing Bag
- Anaesthesia Machine
- Anaesthesia Workstation
- Stethoscope
- **SUCTION MACHINES**
- Electric Suction Machine 1/4 HP (Glass / Polycarbonate Jar)
- Electric Cum Foot Suction Machine (Glass / Polycarbonate Jar)
- Electric Suction Machine 1/2 HP (Glass / Polycarbonate Jar)
- Foot Suction Machine (Glass / Polycarbonate Jar)
- Vertical Foot Suction Machine (Glass / Polycarbonate Jar)
- Portable Suction Machine (Glass / Polycarbonate Jar)
- Ambulance/Battery Operated Suction Machine (Glass / Polycarbonate Jar)
- Liposuction Machine (Glass / Polycarbonate Jar)
- Portable Single Jar Suction Machine (Glass / Polycarbonate Jar)
- Portable Slow Suction (Electric Vacuum Extraction) (Glass / Polycarbonate Jar)
- **INFANT CARE**
- Infant Radiant Warmer (Premium)
- Infant Radiant Warmer (Deluxe)
- Open Care System
- Phototherapy Unit
- Bassinet
- Phototherapy with Stand
- Double Surface Phototherapy
- Patient Warming System
- Infant Resuscitation System
- Intensive Care Incubator
- Transport Intensive Care Incubator
- Phototherapy Light
- Infant Radiant Warmer (Superior Series)
- Infant Radiant Warmer (Prime Series)
- Infant Radiant Warmer (Paramount Series)
- Infant Radiant Warmer (Essential Series)

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## Certificate of Compliance

## Appendix-V

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Applicant :

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Products:

OFFICE: E-117, PREET VIHAR, DELHI - 110092 (INDIA)

OFFICE: B-3/14, PREET VIHAR COMPLEX, DELHI-110092 INDIA

FACTORY:- 51, PATPARGANJ INDUSTRIAL AREA, DELHI - 110 092 (INDIA)



This certificate referred to above covers the following products like:

- **BP MONITOR**
  - Mercury Sphygmomanometer
  - Portable Stand Mercury Sphygmomanometer
  - Aneroid Sphygmomanometer
  - Digital Sphygmomanometer
  - Nebulizer
  - LCD Sphygmomanometer
- Diamond Pencil
- Mucus Sucker
- Ring Pessary
- Plastic Tray
- Corrugated Drainage Sheet
- Rubber Hot Water Bottle
- Rubber Ice Bag
- Blood Pressure Bulb
- BP Cuff
- Pipette Bulb
- Rubber Ear Syringe
- Enema Bulb Syringe
- Enema Syringe
- Douche Spray
- Vaginal Douche Spray
- Bio Hazard Bins
- Bio Hazard Bags
- Sharp Containers
- Waste Containers
- Sickness Bag
- Hand Sanitizer
- Trial Lens Set
- Nebulizer
- Lead Apron
- Delivery Kit Box
- Midwifery Box
- Pet Bowls
- Castors
- Railings
- Fetoscope Aluminium
- Fetoscope Wooden
- Glycerine Syringe
- Dispensing Cup
- Eye Wash Cup

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## Certificate of Compliance

## Appendix-VI

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MAHIKA MEDICAL PVT. LTD.

Products:

OFFICE: E-117, PREET VIHAR, DELHI - 110092 (INDIA)

OFFICE: B-3/14, PREET VIHAR COMPLEX, DELHI-110092 INDIA

FACTORY:- 51, PATPARGANJ INDUSTRIAL AREA, DELHI - 110 092 (INDIA)



This certificate referred to above covers the following products like:

- Steam Inhaler
- Steam Vaporiser
- Washing Bottle
- Precussion Hammer
- Stadiometer
- **Eye Shield**
- Breast Reliever
- Neeti Pot
- Blood Lancets
- ID Bracelet
- Knee Hammer
- Otoscope
- Ophthalmoscope
- Tonometer
- Baby weighing Scale
- Adult Scale
- Bathroom Scale
- Infrared Lamp Portable
- Infrared Lamp Standing
- Infrared Bulb
- Infantometer
- Skin Grafting Handle
- Fetal Doppler
- Eye Testing Drum
- Head Light
- X Ray Hangers
- Umbilical Cord
- Aspiration Kit
- Insulin Syringe
- Insulin Syringe 29G
- Insulin Syringe 30G
- Insulin Syringe 31G
- Insulin Syringe 6mm
- **Insulin Syringe 8mm**
- Insulin Syringe 12.7mm
- IV Cannula
- IV Cannula 14G
- IV Cannula 16G
- IV Cannula 17G
- IV Cannula 18G
- IV Cannula 20G
- IV Cannula 22G
- IV Cannula 24G
- IV Cannula 26G

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## Certificate of Compliance

## Appendix-VII

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OFFICE: B-3/14, PREET VIHAR COMPLEX, DELHI-110092 INDIA

FACTORY:- 51, PATPARGANJ INDUSTRIAL AREA, DELHI - 110 092 (INDIA)



This certificate referred to above covers the following products like:

- IV Set
- Foley Balloon Catheter 2 Way
- Foley Balloon Catheter 3 Way
- Foley Balloon Catheterization Kit
- Nelaton Catheter
- **Male External Catheter Penile Sheath**
- Endotracheal Tube - Cuffed
- Endotracheal Tube - Plain
- Endotracheal Tube - Subglottic Suction Line
- Tracheostomy Tube - Cuffed
- Tracheostomy Tube - Uncuffed
- Suction Catheter Closed System
- Preformed Endotracheal Tube - Cuffed
- Preformed Endotracheal Tube - Plain
- Nasal Oxygen Cannula
- Suction Catheter
- Breathing Exerciser
- HME Filter
- Intubating Stylet
- Thoracic Trocar Catheter
- Thoracic / Chest Drainage Catheter
- Abdominal Drainage Kit
- Chest Bag / Water Sealed Drainage System
- Yankaur Suction Set
- Closed Wound Suction Unit
- Colostomy Bag
- Colostomy Kit
- Salem Sump Tube / Irrigation Tube
- Gastro Duodenal Dual Flow Tube
- Levin's Tube / Stomach Tube
- Ryle's Tube
- Kehr's "T" Tube
- Infant Feeding Tube
- Rectal Catheter

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## Certificate of Compliance

## Appendix-VIII

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FACTORY:- 51, PATPARGANJ INDUSTRIAL AREA, DELHI - 110 092 (INDIA)



This certificate referred to above covers the following products like:

- **3 Way Stop Cock With Extension Line**
- **Pressure Monitoring Line**
  - Microporous Tape
  - Silicon Gel Tape
  - Zinc Oxide Plaster
  - Abdominal Pads
  - Surgical Pad
  - Elastic Adhesive Bandage BP
  - Elastic Adhesive Bandage
- **Manual Vacuum Aspiration (MVA Kit)**
- **Cytobrush /Endocervical Brush**
- **Infant Mucus Extractor**
  - Umbilical Cord Clamp
- **Umbilical Catheter**
  - Urine Specimen Container
  - Stool Specimen Container
- **Blood Lancet**
  - Eye Wash Bottle
- **NEEDLES**
  - Disposable Hypodermic Needle
  - Spinal Anaesthesia Needle
  - Blood Lancet Needle
  - Suture Needle
  - Body Piercing Needle
  - Blade
  - Surgical Blades
- **ANAESTHESIA MACHINE AND WORKSTATION**
  - Anaesthesia Machine 222 Stainless Steel / Boyles Apparatus
  - Anaesthesia Machine 555 Stainless Steel / Boyles Apparatus
  - Anaesthesia Machine 777 Stainless Steel / Boyles Apparatus
  - Anaesthesia Machine 222 Mild Steel / Boyles Apparatus
  - Anaesthesia Machine 555 Mild Steel / Boyles Apparatus
  - Anaesthesia Machine 777 Mild Steel / Boyles Apparatus
  - Anaesthesia Workstation
- **VACCINE CARRIERS AND ACCESSORIES**
  - Vaccine Carrier
  - Cold Box
  - Vaccine Transporter
  - Ice Lined Refrigerators
  - Ice Packs
- **THERMOMETERS**
  - Digital Thermometer
  - Mercury Thermometer
  - Rectal Thermometer
  - Refrigerator Thermometer



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## Appendix-VIII

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Products:

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OFFICE: B-3/14, PREET VIHAR COMPLEX, DELHI-110092 INDIA

FACTORY:- 51, PATPARGANJ INDUSTRIAL AREA, DELHI - 110 092 (INDIA)



This certificate referred to above covers the following products like:

- PHYSIOTHERAPY AND HEALTHCARE MACHINES
- TENS 4 Channel
- Ultrasonic 1 & 3 MHz
- Ultrasonic Digital
- Ultrasonic Mini
- Muscle Simulator Diagnostic
- Mole and Wart Remover
- Short Wave Diathermy
- Digital Traction
- Manual Traction
- CPM

- LCD CPM
- IFT
- Computerised IFT
- Laser Therapy
- Ultrasonic
- Mini TENS
- Muscle Simulator
- MS + TENS
- US + TENS
- MS + TENS
- IFT + MS + TENS
- IFT + US + TENS
- IFT + US + MS
- US + TENS
- IFT + US + MS + TENS
- LCD
- Slimmer
- Long Wave Therapy
- Vacuum Therapy
- Deep Heat Therapy
- Massager
- Liposuction
- Face Lifting
- Laser Hair Removal Machine
- Shock wave Therapy
- Cryolysis Machine
- Laser Machine
- Hi-Low Treatment Table
- Traction Table
- Tilt Table
- Hydrocollator
- IR Lamp

• **ELECTROSURGICAL CAUTERY AND ACCESSORIES**

- Cautery 100 watt
- Pen Type cautery
- Cautery Smart 250 watt Digital
- Cautery SSE 300 watt analog
- Cautery SSE TUR 400 Watt Analog
- Cautery Smart 3, 300 watt digital

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## Appendix-VIII

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Products:

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FACTORY:- 51, PATPARGANJ INDUSTRIAL AREA, DELHI - 110 092 (INDIA)



This certificate referred to above covers the following products like:

- **ELECTROSURGICAL CAUTERY AND ACCESSORIES**
  - Cautery Smart 4, 400 watt digital
  - Cautery Smart 4+, Advanced 400 watt digital
  - BISEAL150, Seal with Bipolar
  - BITUR, Normal Saline Turp
  - BITUR + Cautery, Normal Saline Bipolar Turp 400W Cautery
  - Mono Seal Prime 400 watt digital cautery with vessel sealing system
  - Crown 400 watt digital cautery with vessel sealing system and normal saline bipolar TURP
  - CO2 Insufflator
  - Light Source

### MEDICAL ELECTRONICS

Pulse Oximeter

ECG Machine

Fetal Doppler

Fetal Monitor

Ventilator

CPAP System

Infusion Pump

Syringe Pump

Defibrillator

Oxygen Concentrator

BIPAP

DVT Pump

Patient Warmer

Tourniquet Machine

AED

Spirometer

Patient Monitor



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