



सत्यमेव जयते

FORM MD-5

[See sub-rule (4) of rule 20 and sub-rule (6) of rule 20]

Licence to Manufacture for Sale or for Distribution of Class A or Class B medical device

Licence Number: **MFG/MD/2023/000147**

Endorsement No. **3**

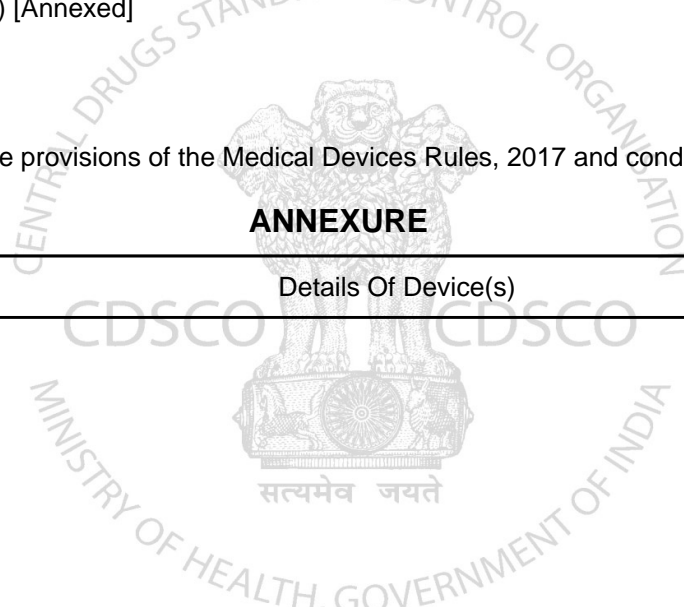
1. **M/s Anaesthetics India Pvt Ltd, Unit 8, Gala No 8, E. D. Estate, Off Kaman Bhiwandi Highway, Chincholi, Vasai (East)VASAI, Thane, Maharashtra (India) - 401208 Telephone No.: 9833737036 FAX: 9022917032** has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at **M/s Anaesthetics India Pvt Ltd, Unit 8, Gala No 8, E. D. Estate, Off Kaman Bhiwandi Highway, Chincholi, Vasai (East) , Thane, Maharashtra (India) - 401208 Telephone No.: 9833737036 FAX: 9022917032**

2. Details of medical device(s) [Annexed]

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

ANNEXURE

S.No.	Details Of Device(s)
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1

Generic Name:Laryngoscope

Model No.:6102 Paediatric Laryngoscope Set - Penlite Handle With Miller Bright finish Blade Size 0 1 and 2 Nos Spare Lamp all in a Carrying Case ,6102M Paediatric Laryngoscope Set - Penlite Handle With Miller Matt finish Blade Size 0 1 and 2 Nos Spare Lamp all in a Carrying Case ,6103 Neonatal Laryngoscope Set - Penlite Handle With Miller Bright finish Blade Size 00 0 1 and 3 Nos Spare Lamp all in a Carrying Case ,6104 Paediatric Laryngoscope 4 Blade Set - Penlite Handle With Miller Bright finish Blade Size 00 0 1 2 and 4 Nos Spare Lamp all in a Carrying Case ,6203 Adult Laryngoscope 3 Blade Set - Standard Handle With Macintosh Bright finish Blade Size 1 2 3 and 3 Nos Spare Lamp all in a Carrying Case ,6203M Adult Laryngoscope 3 Blade Set - Standard Handle With Macintosh Matt finish Blade Size 1 2 3 and 3 Nos Spare Lamp all in a Carrying Case ,6204 Adult Laryngoscope 4 Blade Set - Standard Handle With Macintosh Bright finish Blade Size 1 2 3 4 and 4 Nos Spare Lamp all in a Carrying Case ,6204M Adult Laryngoscope 4 Blade Set - Standard Handle With Macintosh Matt finish Blade Size 1 2 3 4 and 4 Nos Spare Lamp all in a Carrying Case ,6112 LED Laryngoscope Paediatric Set - Penlite Handle With LED Miller Blade Size 0 and 1 all in a Carrying Case ,6113 LED Laryngoscope Neonatal Set - Penlite Handle With LED Miller Blade Size 00 0 and 1 all in a Carrying Case ,6114 LED Laryngoscope Paediatric 4 Blade Set - Penlite Handle With LED Miller Blade Size 00 0 1 and 2 all in a Carrying Case ,6213 LED Laryngoscope Adult 3 Blade Set - Standard Handle With LED Macintosh Blade Size 1 2 and 3 all in a Carrying Case ,6214 LED Laryngoscope Adult 4 Blade Set - Standard Handle With LED Macintosh Blade Size 1 2 3 and 4 all in a Carrying Case ,6106 Fibrelite Laryngoscope Paediatric - Penlite Handle With Fibrelite Miller Blade Size 0 1 and 2 Nos. Spare Lamp and Lamp Key all in a Carrying Case ,6207 Fibrelite Laryngoscope Adult 3 Blade - Standard Handle With Fibrelite Macintosh Blade Size 1 2 3 and 3 Nos. spare Lamp and Lamp key all in a Carrying Case ,6208 Fibrelite Laryngoscope Adult 4 Blade - Standard Handle With Fibrelite Macintosh Blade Size 1 2 3 4 and 4 Nos. spare Lamp and Lamp key all in a Carrying Case ,6108 Green System Fibreoptic Laryngoscope Paediatric - Green System Penlite Handle With Green system Fibreoptic Miller Blade Size 0 and 1 all in a Carrying Case ,6109 Green System Fibreoptic Laryngoscope Neonatal - Green System Penlite Handle With Green system Fibreoptic Miller Blade Size 00 0 and 1 all in a Carrying Case ,6210 Green System Fibreoptic Laryngoscope Adult 3 Blade - Green System Standard Handle With Green system Fibreoptic Macintosh Blade Size 1 2 and 3 all in a Carrying Case ,6211 Green System Fibreoptic Laryngoscope Adult 4 Blade - Green System Standard Handle With Green system Fibreoptic Macintosh Blade Size 1 2 3 and 4 all in a Carrying Case ,6834 MRI Laryngoscope Adult - Standard Handle with Battery and MRI Macintosh Blade Size 1 2 3 and 4 all in a Carrying Case ,6828 MRI Laryngoscope Adult - Penlite Handle with Battery and MRI Miller Blade Size 00 0 1 and 2 all in a Carrying Case ,6360 Video Laryngoscope Set - Polycarbonate Blade Size 1 2 3 4 2 Nos. each Size all in a carrying case ,6370 Video Laryngoscope Set - Metal Reusable Macintosh Blade Size 2 3 4 all in a carrying case

Intended Use:The laryngoscope is intended for providing a visual pathway to the larynx during intubation procedures. It aids healthcare professionals in accurately visualizing and positioning the endotracheal tube in the trachea by displaying a real-time image on the integrated screen. This device aims to improve intubation success rates, reduce complications, and enhance patient safety during airway management in hospital, pre-hospital, and emergency care settings. When connected through a camera-assisted system it also enhances visualization, particularly beneficial in managing difficult airways.

Class of medical device:Class A

Material of construction:Stainless Steel Body, Handle Brass chrome plated, PVC

Dimension(if any):

Shelflife:NIL

Sterile or Non sterile:Non-Sterilized

Brand Name(if registered under the Trade Marks Act, 1999):Anaesthetics

2	<p>Generic Name:Intubation Instruments Model No.:7103 (7103A to 7103G) PVC Disposable Guedel Airway - Size 000 Length X 35mm to Size 4 Length X 110mm,7102 (7102A to 7102AD) Guedel Airway Silicone Rubbe - Size 000 Length X 35mm to Size 4 Length X 110mm,7225 (7225A to 7225C) Fibrelite Stylets - Length - 170mm to Length - 18 inch,7201 (7201A to 7201C) Malleable Stylet - 215 mm to 390 mm,7210 Bougie Adult - 4mm X 700mm ,7204 Magill Forceps - Length - 250mm,7205 Magill Forceps - Length - 200mm,7206 Magill Forceps - Length - 170mm,7211 Bougie Paediatric - 3mm X 500mm,7214 Ventilating Bougie Adult - 5mm X 700mm,7101 (7101A to 7101D) Guedel Airway Silicone Rubber - Length - 65mm to Length - 110mm</p> <p>Intended Use:The intubation instruments are intended to facilitate the safe and effective management of a patient’s airway during surgical, anesthetic, or emergency situations. They are used to assist in maintaining airway patency, guiding endotracheal tube placement, and removing obstructions or guiding devices in the airway.</p> <p>Class of medical device:Class A Material of construction:Silicone Rubber, PVC, Stainless Steel Dimension(if any): Shelflife:NIL Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Anaesthetics</p>
3	<p>Generic Name: Medical Gas Therapy Equipment Model No.:3008 Gas Regulator - H-220mm X W-130mm X L-130mm ,3503 Two Stage Gas Regulator - H-180mm X W-180mm X L-180mm ,3027 Twin Gauge Gas Regulator - H-210mm X W-130mm X L-130mm ,3005 (Fine Adjustment) Valve - H-150mm X W-170mm X L-60mm ,3045 Air Regulator - H-220mm X W-130mm X L-130mm ,3509 Two Stage Nitrogen Regulator - H-180mm X W-180mm X L-180mm , 3680 Nitrous Oxide Regulator - H-220mm X W-130mm X L-130mm ,3044 Carbon dioxide Regulator - H-180mm X W-180mm X L-180mm ,3137 - Gas Gauge - Range 0 to 16Kg/cm2 (50mm Dia) ,3113 - Gas Gauge - Range 0 to 250Kg/cm2 (50mm Dia) , 3761 - Nitrous Oxide Gauge - Range 0 to 16Kg/cm2 (50mm Dia) ,3762 - Nitrous Oxide Gauge - Range 0 to 250Kg/cm2 (50mm Dia) ,Nitrogen Gauge - Range 0 to 16Kg/cm2 (50mm Dia) ,Nitrogen Gauge - Range 0 to 250Kg/cm2 (50mm Dia) ,3146 - Air Gauge - Range 0 to 16Kg/cm2 (50mm Dia) ,3143 - Air Gauge - Range 0 to 250Kg/cm2 (50mm Dia) ,3145 - Carbon Dioxide Gauge - Range 0 to 16Kg/cm2 (50mm Dia) ,3144 - Carbon Dioxide Gauge - Range 0 to 250Kg/cm2 (50mm Dia) , 3326 - Gas Gauge - Range 0 to 16Kg/cm2 (100mm Dia) ,3324 - Gas Gauge - Range 0 to 250Kg/cm2 (100mm Dia) ,3041 - BPC Flowmeter Unit - Brass Body ,3010 - BPC Flowmeter Unit - Plastic Body ,3006 - Flowmeter unit for F/A Valve ,3014 - Gas Nasal Cannula Size Adult ,3015 - Gas Nasal Cannula Size Child ,3016 - Gas Nasal Cannula Size Infant ,3017 - Gas Mask Plain Size Adult ,3018 - Gas Mask Plain Size Child ,3020 - Gas Mask with percentage Control Size Adult ,3021 - Gas Mask with percentage Control Size Child ,3037 - High Concentration Mask Size Adult ,3038 - High Concentration Mask Size Child ,3031 - Gas Mask with Nebulizer Size Adult ,3032 - Gas Mask with Nebulizer Size Child ,3039 - Nebulizer Mouth Kit</p> <p>Intended Use:Medical Gas therapy equipment is intended to facilitate the safe delivery of Medical Gas medical gas to patients with compromised respiratory function. It regulates Medical Gas pressure, measures gas supply levels, and ensures accurate flow rates to meet the therapeutic needs of the patient.</p> <p>Class of medical device:Class A Material of construction:Brass, Stainless Steel, Antistatic Rubber Dimension(if any): Shelflife:NIL Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Anaesthetics</p>

4	<p>Generic Name:Hospital Pipeline Accessories</p> <p>Model No.:3460 - Terminal Unit Oxygen - BOC Type ,3461 - Terminal Unit Nitrous Oxide - BOC Type ,3462 - Terminal Unit Air - BOC Type ,3463 - Terminal Unit Vacuum - BOC Type ,3450 - 3/8inch BSP Threaded Direct Probe Oxygen - BOC Type , 3470 - Tube Fitting Direct Probe Oxygen - BOC Type ,3471 - Tube Fitting Direct Probe Nitrous Oxide - BOC Type ,3472 - Tube Fitting Direct Probe Air - BOC Type , 3473 - Tube Fitting Direct Probe Vacuum - BOC Type ,3421 - Terminal Unit Oxygen - DIN Standard ,3422 - Terminal Unit Nitrous Oxide - DIN Standard ,3423 - Terminal Unit Air - DIN Standard ,3424 - Terminal Unit Vacuum - DIN Standard ,3426 - 3/8inch BSP Threaded Direct Probe Oxygen - DIN Standard ,3427 - Tube Fitting Direct Probe Oxygen -DIN Standard ,3428 - Tube Fitting Direct Probe Nitrous Oxide -DIN Standard ,3429 - Tube Fitting Direct Probe Air -DIN Standard ,3430 - Tube Fitting Direct Probe Vacuum -DIN Standard ,3315 - S Bracket ,3303 - Self Sealing Valve Oxygen ,3304 - Self Sealing Valve Nitrous Oxide ,3305 - Self Sealing Valve Air ,3306 - Self Sealing Valve Vacuum ,3307 - Safety Key Oxygen ,3308 - Safety Key Nitrous Oxide ,3309 - Safety Key Air ,3310 - Safety Key Vacuum ,3311 - Plastic Cover Oxygen ,3312 - Plastic Cover Nitrous Oxide ,3313 - Plastic Cover Air ,3314 - Plastic Cover Vacuum , 3316 - Button for Cover ,3301 - Single Pipeline Adaptor,3302 - Twin Pipeline Adaptor,3726 - High Pressure Tubing - Oxygen,3429 - High Pressure Tubing - Nitrous Oxide,3730 - High Pressure Tubing - Air,1211 - High Pressure Tubing - Vacuum,1203 - Vacuum High Pressure Regulator - 0 to 760mm Hg. ,1220 - Vacuum Medium Pressure Regulator - 0 to 500mm Hg. ,1230 - Vacuum Low Pressure Regulator - 0 to 200mm Hg. ,1100 - Theatre Vacuum Trolley with 2000ml Jar ,1200 - Theatre Vacuum Trolley with 4000ml Jar,1250 - Ward Vacuum Unit without Regulator - 600ml ,1201 - Ward Vacuum Unit without Regulator - 1000ml ,1202 - Ward Vacuum Unit without Regulator - 2000ml ,1260 - Ward Vacuum Unit without Regulator - 4000ml , 1101 - Hand Suction Unit - 40ml ,1102 - Hand Suction Unit - 100ml</p> <p>Intended Use:To enable safe, quick, and secure connection and disconnection of oxygen or medical gas supply in hospital settings.</p> <p>Class of medical device:Class A</p> <p>Material of construction:Brass, Stainless Steel, Plastics</p> <p>Dimension(if any):</p> <p>Shelflife:NIL</p> <p>Sterile or Non sterile:Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):Anaesthetics</p>
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Place:

Date06-Dec-24

State Licensing Authority