



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. 2

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)
1	<p>Generic Name:Resuscitators Model No.:5001 Rao Adult Resuscitator - 300mm X 160 mm X 100mm ,5002 Rao Large Child Resuscitators - 300mm X 160 mm X 100mm ,5003 Rao Child Resuscitators - 300mm X 160 mm X 100mm ,5004 Rao Infant Resuscitators - 300mm X 160 mm X 100mm Intended Use:Single patient use, manual resuscitator for use in hospital, transport, emergency, and post-hospital care to temporary ventilate a patient. Class of medical device:Class B Material of construction:Siliconer Rubber, Poly Carbonate, PVC Dimension(if any):300mm X 160 mm X 100mm Shelflife:NIL Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Anaesthetics</p>

2	<p>Generic Name:Humidifier</p> <p>Model No.:3013 - Humidifier with "S" hook type 250ml Capacity polycarbonate Jar with minium & maximum water level marking ,3012 - Humidifier Screw on type 250ml Capacity polycarbonate Jar with minium & maximum water level marking ABS Plastic Cap,3050A - Humidifier Screw on type (Metal Inlet & Outlet) 250ml Capacity polycarbonate Jar with minium & maximum water level marking ABS Plastic Cap with Metal Inlet & Outlet Plastic washer PP inner pipe with diffuser.,3051A - Humidifier for Oxygen Generator (Metal Inlet & Outlet) 250ml Capacity polycarbonate Jar with minium & maximum water level marking ABS Plastic Cap with Metal Female Nut Inlet & Nossle type Outlet Plastic washer PP inner pipe with diffuser.,3052 - Humidifier for oxygen generator - Disposable 450ml Capacity Polyproplyne Jar with minium & maximum water level marking Plastic Cap with relief valve.</p> <p>Intended Use:Humidifiers are intended to add moisture to Oxygen delivered to spontaneously breathing patients requiring assisted breathing and / or mucosal humidification for patients in hospitals and at home.</p> <p>Class of medical device:Class B</p> <p>Material of construction:Polycarbonate, ABS, PP, Brass</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>
3	<p>Generic Name:Tracheal Stenosis Tube</p> <p>Model No.:7901A TRACHEAL STENOSIS TUBE - 8mm OD X 6mm ID X 40mm Length ,7901B TRACHEAL STENOSIS TUBE - 8mm OD X 6mm ID X 40mm Length ,7901C TRACHEAL STENOSIS TUBE - 8mm OD X 6mm ID X 40mm Length ,7902A TRACHEAL STENOSIS TUBE - 10mm OD X 8mm ID X 40mm Length ,7902B TRACHEAL STENOSIS TUBE - 10mm OD X 8mm ID X 40mm Length ,7902C TRACHEAL STENOSIS TUBE - 10mm OD X 8mm ID X 40mm Length ,7903A TRACHEAL STENOSIS TUBE - 12mm OD X 9mm ID X 40mm Length ,7903B TRACHEAL STENOSIS TUBE - 12mm OD X 9mm ID X 40mm Length ,7903C TRACHEAL STENOSIS TUBE - 12mm OD X 9mm ID X 40mm Length ,7904A TRACHEAL STENOSIS TUBE - 14mm OD X 11mm ID X 40mm Length ,7904B TRACHEAL STENOSIS TUBE - 14mm OD X 11mm ID X 40mm Length ,7904C TRACHEAL STENOSIS TUBE - 14mm OD X 11mm ID X 40mm Length</p> <p>Intended Use:A device intended to maintain tracheostoma patency after repeated use of tracheostomy devices which cause scar tissue to the trachea and to prevent tracheostomal stenosis.</p> <p>Class of medical device:Class B</p> <p>Material of construction:Silicone Rubber</p> <p>Dimension(if any):OD of 8 MM, 10 MM, 12 MM and 14 MM</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>

4	<p>Generic Name:Nasopharyngeal Airways</p> <p>Model No.:7125D SILICONE RUBBER NASOPHARYNGEAL AIRWAYS - ID - 4mm ,7125E SILICONE RUBBER NASOPHARYNGEAL AIRWAYS - ID - 5mm ,7125F SILICONE RUBBER NASOPHARYNGEAL AIRWAYS - ID - 6mm ,7125G SILICONE RUBBER NASOPHARYNGEAL AIRWAYS - ID - 7mm ,7125H SILICONE RUBBER NASOPHARYNGEAL AIRWAYS - ID - 8mm , 7125I SILICONE RUBBER NASOPHARYNGEAL AIRWAYS - ID - 9mm</p> <p>Intended Use:A rubber or plastic tube that extends into the pharynx from either naris to maintain airway patency in cases where oropharyngeal airways cannot be used.</p> <p>Class of medical device:Class B</p> <p>Material of construction:Silicone Rubber</p> <p>Dimension(if any):ID 04 MM to 09 MM</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-Jul-23

State Licensing Authority

