



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. 1

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	<p>Generic Name:Anaesthesia breathing circuit</p> <p>Model No.:2021 Bain Mapleson Circuit - 22mm Corrugated Hose 6mm Green PVC Tubing End Mount Distal End Mount Spill Valve 2 Ltr. Bag 15mm/22mm Swivel Angle Mount Safety Cap 22mm/23mm M/M Adaptor 22mm/22mm M/M Adaptor 22mm/23mm M/F Adaptor,2029 Mapleson C type Circuit - 10mm Corrugated PI Hose 22mm T piece with Swivel Spill Valve Safety Cap 22mm Bag Mount 2 Ltr. Breathing Bag 10mm/22mm M/M Adaptor 15mm/22mm F/F Adaptor 22mm/23mm M/M Adaptor 15mm/22mm Swivel Angle Mount 6-9mm E. Soft Connector,2008 Anaesthesia Paediatric Circuit Infant T Piece System - 10mm Corrugated Plastic Hose 15mm Corrugated Plastic Hose 15mm/22mm Paedi Angle Mount with Swivel Safety Cap 10mm/22mm M/M Circuit Adaptor 0.5 Ltr. Breathing Bag Bag Bleed Valve 15mm/15mm M/M Circuit Adaptor 15mm/22mm F/F Circuit Adaptor 22mm/23mm M/M Circuit Adaptor 6-9mm Elastometric Soft Connector,2028 Paediatric Circuit Jackson Rees T Piece System - 10mm Corrugated Plastic Hose 15mm Corrugated Plastic Hose 15mm T piece with Swivel 15mm/22mm Swivel Angle Mount Safety Cap 10mm/22mm M/M Circuit Adaptor 15mm/15mm M/M Circuit Adaptor 0.5 Ltr. Breathing Bag Bag Bleed Valve 15mm/22mm F/F Circuit Adaptor 22mm/23mm M/M Circuit Adaptor 6-9mm Elastometric Soft Connector,2019 Anaesthesia Circuit Adult with 2 Port Wye - 22mm Corrugated Plastic Hose 2 Port Wye – Adult 22mm/22mm M/F Circuit Adaptor 15mm/22mm Swivel Angle Mount Safety Cap 22mm/22mm M/M Circuit Adaptor Breathing Bag 22mm/23mm M/M Circuit Adaptor</p> <p>Intended Use:An assembly of devices designed to conduct medical gases from the fresh gas supply outlet of an anaesthesia unit/workstation to the patient.</p> <p>Class of medical device:Class B</p> <p>Material of construction:PVC, Polypropelyne</p> <p>Dimension(if any):Various</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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2	<p>Generic Name: Ventilator Circuit</p> <p>Model No.: 2009 Ventilator Circuit Plain Adult - 22mm Corrugated Plastic Hose Fixed Wye Adult 22mm/22mm Male/Female Circuit Adaptor 15mm/22mm Swivel Angle Mount Safety Cap ,2009W Ventilator Circuit Adult with 1 Water Trap &amp; Limb - 22mm Corrugated Plastic Hose 2 Port Wye – Adult 22mm/22mm Male/Female Circuit Adaptor 22mm/22mm Male/Male Circuit Adaptor Water Trap 15mm/22mm Swivel Angle Mount Safety Cap ,2009DW Ventilator Circuit Adult with 2 Water Trap &amp; Limb - 22mm Corrugated Plastic Hose 2 Port Wye – Adult 22mm/22mm Male/Female Circuit Adaptor 22mm/22mm Male/Male Circuit Adaptor Water Trap 15mm/22mm Swivel Angle Mount Safety Cap ,2011 Ventilator Circuit - Paediatric - 15mm Corrugated Plastic Hose Fixed Paedi Wye 15mm/22mm Swivel Angle Mount 22mm Female Catheter Mount Safety Cap ,2011W Ventilator Circuit - Paediatric with 1 Water Trap &amp; Limb - 15mm Corrugated Plastic Hose 2 Port Paedi Wye 22mm Female Catheter Mount Water Trap 22mm/22mm Male/Male Circuit Adaptor 15mm/22mm Swivel Angle Mount Safety Cap , 2011DW Ventilator Circuit - Paediatric with 2 Water Trap &amp; Limb - 15mm Corrugated Plastic Hose 2 Port Paedi Wye 22mm Female Catheter Mount Water Trap 22mm/22mm Male/Male Circuit Adaptor 15mm/22mm Swivel Angle Mount Safety Cap ,2012 Ventilator Circuit - Neonatal - 10mm Corrugated Plastic Hose – Green 10mm Corrugated Plastic Hose – White 1 Port Neonatal Wye Temp. Port 10mm/22mm Male/Male Circuit Adaptor 9-11mm Soft Mount 6-9mm Elastometric Soft Connector Monitoring Line Tube 15mm/22mm Female/Female Circuit Adaptor ,2012DW Ventilator Circuit - Neonatal with 2 Water Trap - 10mm Corrugated Plastic Hose – Green 10mm Corrugated Plastic Hose – White 1 Port Neonatal Wye Temp. Port 10mm/22mm Male/Male Circuit Adaptor 9-11mm Soft Mount 6-9mm Elastometric Soft Connector Monitoring Line Tube Neonatal Moisture Trap 15mm/22mm Female/Female Circuit Adaptor</p> <p>Intended Use: Ventilator circuit is intended as a conduit for respiratory gas between a patient and a ventilator.</p> <p>Class of medical device: Class B</p> <p>Material of construction: Polypropylene</p> <p>Dimension(if any): Various</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:

Date 31-Mar-23

State Licensing Authority