



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/2019/000084

Endorsement No. 1

1. M/s Life O Line Technologist, Plot NO. 864/1 Paiki, Nr. IOCL Petrol Pump, Ahmedabad-Mehmedabad Road PO And AT Hirapur Village, Ahmedabad, Gujarat (India) - 380445 Telephone No.: 9898162576 FAX: 9898162576 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s Life O Line Technologist, Plot NO. 864/1 Paiki, Nr. IOCL Petrol Pump, Ahmedabad-Mehmedabad Road ,PO And AT Hirapur Village, Ahmedabad, Gujarat (India) - 380445 Telephone No.: 9898162576 FAX: 9898162576

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	Generic Name:Nasal Cannula Model No.:Nasal Canula-A - ADULT / PAED / NEON ,Nasal Canula-N - ADULT / PAED / NEON Intended Use:The nasal cannula (NC) is a device used to deliver supplemental oxygen or increased airflow to a patient or person in need of respiratory help. Class of medical device:Class A Material of construction:PVC Dimension(if any):NA Shelflife:3 Years Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Life-o-med
2	Generic Name:OXYGEN MASK WITH TUBING Model No.:NIL Intended Use:intended to deliver supplemental oxygen to patients and monitor breathing by sampling exhaled carbon dioxide. Class of medical device:Class A Material of construction:PVC & HDPE Dimension(if any):NA Shelflife:3 Years Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Life-o-med

3	<p>Generic Name:HIGH CONCENTRATION MASK  Model No.:NIL  Intended Use:High concentration masks intended for administration of oxygen. They are equipped with a reservoir bag allowing an adequate amount of oxygen to be available to meet unpredictable breathing patterns and tidal volumes.  Class of medical device:Class A  Material of construction:PVC &amp; HDPE  Dimension(if any):NA  Shelflife:3 Years  Sterile or Non sterile:Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):Life-o-med</p>
4	<p>Generic Name:MULTIFLOW VENTURY MASK  Model No.:NIL  Intended Use:intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation with or without air/oxygen blending.  Class of medical device:Class A  Material of construction:PVC, HDPE &amp; PP  Dimension(if any):NA  Shelflife:3 Years  Sterile or Non sterile:Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):Life-o-med</p>
5	<p>Generic Name:SINGLE DIAL VENTURY MASK  Model No.:NIL  Intended Use:intended for delivering supplemental oxygen and monitoring exhaled carbon dioxide in non-intubated spontaneously breathing patients. Standard oxygen tubing and two female Luer ports for gas sample line attachment are included.  Class of medical device:Class A  Material of construction:PVC, HDPE &amp; PP  Dimension(if any):NA  Shelflife:3 Years  Sterile or Non sterile:Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):Life-o-med</p>
6	<p>Generic Name:HME Filter  Model No.:NIL  Intended Use:used for humidification and bacterial/viral filtration during anesthesia and ventilator care.  Class of medical device:Class B  Material of construction:PP, PP SPUNCH  Dimension(if any):NA  Shelflife:3 Years  Sterile or Non sterile:Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):Life-o-med</p>

7	<p>Generic Name: BVF Filter  Model No.: NIL  Intended Use: used for humidification and bacterial/viral filtration during anesthesia and ventilator care.  Class of medical device: Class B  Material of construction: PP, NON WOVEN  Dimension(if any): NA  Shelflife: 3 Years  Sterile or Non sterile: Sterilized  Brand Name(if registered under the Trade Marks Act, 1999): Life-o-med</p>
8	<p>Generic Name: BVF HME Filter  Model No.: NIL  Intended Use: used for humidification and bacterial/viral filtration during anesthesia and ventilator care.  Class of medical device: Class B  Material of construction: PP, NON WOVEN  Dimension(if any): NA  Shelflife: 3 Years  Sterile or Non sterile: Sterilized  Brand Name(if registered under the Trade Marks Act, 1999): Life-o-med</p>
9	<p>Generic Name: Hypodermic Syringe with Needle &amp; W/o Needle  Model No.: NIL  Intended Use: intended to be used for medical purposes to inject fluids into or withdraw fluids from the body.  Class of medical device: Class B  Material of construction: PP  Dimension(if any): NA  Shelflife: 3 Years  Sterile or Non sterile: Sterilized  Brand Name(if registered under the Trade Marks Act, 1999): Life-o-med</p>
10	<p>Generic Name: OXYGENATOR WITH TUBE  Model No.: NIL  Intended Use: used to exchange gases between blood and a gaseous environment to satisfy the gas exchange needs of a patient during cardiopulmonary bypass surgery for periods up to 6 hours.  Class of medical device: Class A  Material of construction: ABS &amp; PVC  Dimension(if any): NA  Shelflife: 3 Years  Sterile or Non sterile: Sterilized  Brand Name(if registered under the Trade Marks Act, 1999): Life-o-med</p>

1 1	<p>Generic Name: VENTILATOR CIRCUIT - PLAIN</p> <p>Model No.: VENTILATOR CIRCUIT - PLAIN - A - ADULT / PAED / NEON , VENTILATOR CIRCUIT - PLAIN - P - ADULT / PAED / NEON , VENTILATOR CIRCUIT - PLAIN - N - ADULT / PAED / NEON</p> <p>Intended Use: During expiration, the gases in the patient's lungs empty into the bellows, making the bellows rise up. The rising bellows pushes out the "used up" driving gas (oxygen) through ventilator controller into the atmosphere. Ventilator circuit is a medical device used to deliver oxygen, remove carbon dioxide, and deliver inhalational anaesthetic agents to a patient.</p> <p>Class of medical device: Class B</p> <p>Material of construction: HDPE, PP</p> <p>Dimension(if any): NA</p> <p>Shelflife: 3 Years</p> <p>Sterile or Non sterile: Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999): Life-o-med</p>
12	<p>Generic Name: VENTILATOR CIRCUIT - SWT</p> <p>Model No.: NIL</p> <p>Intended Use: provides continuous or intermittent ventilatory support for patients weighing more than 5kg (11 lb) who require mechanical ventilation.</p> <p>Class of medical device: Class B</p> <p>Material of construction: HDPE, PP &amp; K RESIN</p> <p>Dimension(if any): NA</p> <p>Shelflife: 3 Years</p> <p>Sterile or Non sterile: Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999): Life-o-med</p>
13	<p>Generic Name: VENTILATOR CIRCUIT - DWT</p> <p>Model No.: NIL</p> <p>Intended Use: intended for neonatal and infant patients in professional healthcare environments as a conduit for respiratory gas between a patient and a ventilator or Infant Flow Generator (for single limb configuration) and include heated wire(s) for use with the Hudson RCI Neptune Heated Humidifier.</p> <p>Class of medical device: Class B</p> <p>Material of construction: HDPE, PP &amp; K RESIN</p> <p>Dimension(if any): NA</p> <p>Shelflife: 3 Years</p> <p>Sterile or Non sterile: Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999): Life-o-med</p>
14	<p>Generic Name: VENTILATOR KIT</p> <p>Model No.: NIL</p> <p>Intended Use: for the continuous or intermittent mechanical ventilatory support of patients weighing at least 5 kg who require mechanical ventilation. The ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician.</p> <p>Class of medical device: Class B</p> <p>Material of construction: HDPE, PP &amp; K RESIN</p> <p>Dimension(if any): NA</p> <p>Shelflife: 3 Years</p> <p>Sterile or Non sterile: Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999): Life-o-med</p>

15	<p>Generic Name:RESUSCITATOR (SILICON) / AMBU BAG  Model No.:NIL  Intended Use:intended for manual pulmonary resuscitation and emergency respiratory support. For use by CPR-trained personnel only, in hospital and pre-hospital settings  Class of medical device:Class B  Material of construction:PC, SILICON  Dimension(if any):NA  Shelflife:3 Years  Sterile or Non sterile:Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):Life-o-med</p>
16	<p>Generic Name:3 BALL Spirometer  Model No.:NIL  Intended Use:intended as an inspiratory deep breathing positive exerciser. Intended for single-patient, multi-use in a hospital or home care setting.  Class of medical device:Class A  Material of construction:PS &amp; HDPE  Dimension(if any):NA  Shelflife:3 Years  Sterile or Non sterile:Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):Life-o-med</p>
17	<p>Generic Name:BAINS CIRCUIT  Model No.:NIL  Intended Use:A breathing system or breathing circuit is a medical device used to deliver oxygen, remove carbon dioxide, and deliver inhalational anaesthetic agents to a patient.  Class of medical device:Class A  Material of construction:HDPE , PP &amp; ABS  Dimension(if any):NA  Shelflife:3 Years  Sterile or Non sterile:Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):Life-o-med</p>
18	<p>Generic Name:ANETHESIA MASK / CUSION MASK  Model No.:NIL  Intended Use:intended for the administration of a gas mixture coming through devices for artificial ventilation  Class of medical device:Class B  Material of construction:PP &amp; PVC  Dimension(if any):NA  Shelflife:3 Years  Sterile or Non sterile:Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):Life-o-med</p>

19	<p>Generic Name: B.PAPE / C.PAPE MASK  Model No.: NIL  Intended Use: Bi-level positive airway pressure (BiPAP) therapy is often used in the treatment of chronic obstructive pulmonary disease (COPD). COPD is an umbrella term for lung and respiratory diseases that make breathing difficult.  Class of medical device: Class B  Material of construction: PP, ABS PVC  Dimension(if any): NA  Shelflife: 3 Years  Sterile or Non sterile: Sterilized  Brand Name(if registered under the Trade Marks Act, 1999): Life-o-med</p>
20	<p>Generic Name: Laryngeal Mask Airways (L.M.A)  Model No.: NIL  Intended Use: indicated for use via a rigid or semi-rigid endoscope with a straight working channel, for the fragmentation of urinary tract (i.e. kidney, ureter and bladder) stones.  Class of medical device: Class B  Material of construction: SILICON &amp; PVC  Dimension(if any): NA  Shelflife: 3 Years  Sterile or Non sterile: Sterilized  Brand Name(if registered under the Trade Marks Act, 1999): Life-o-med</p>
21	<p>Generic Name: B.P. METER  Model No.: NIL  Intended Use: "intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist. The cuff circumference is limited to 14cm-25cm."  Class of medical device: Class B  Material of construction: PP, MERCURY  Dimension(if any): NA  Shelflife: NIL  Sterile or Non sterile: Non-Sterilized  Brand Name(if registered under the Trade Marks Act, 1999): Life-o-med</p>
22	<p>Generic Name: SILICON CAP (SUCTION SET)  Model No.: NIL  Intended Use: The Suction and Irrigation Set is intended for use in laparoscopic gynaecologic, general, thoracic and urology procedures to provide suction and irrigation functions to help flush blood and tissue debris from the operative site during laparoscopy to aid visualization.  Class of medical device: Class B  Material of construction: SILICON &amp; SS  Dimension(if any): NA  Shelflife: 3 Years  Sterile or Non sterile: Sterilized  Brand Name(if registered under the Trade Marks Act, 1999): Life-o-med</p>

23	<p>Generic Name:URINE BAG  Model No.:NIL  Intended Use:Urine collection bags are attached to the end of the catheter to collect urine as it flows from the bladder.  Class of medical device:Class A  Material of construction:PVC, HDPE &amp; PP  Dimension(if any):NA  Shelflife:For Non Sterile (NIL) / For Sterile (3 Years)  Sterile or Non sterile:Both  Brand Name(if registered under the Trade Marks Act, 1999):Life-o-med</p>
24	<p>Generic Name:NASOPHARYNGEAL AIRWAYS  Model No.:NIL  Intended Use:An oropharyngeal airway (oral airway, OPA) is an airway adjunct used to maintain or open the airway by stopping the tongue from covering the epiglottis. In this position, the tongue may prevent an individual from breathing.  Class of medical device:Class A  Material of construction:LATEX  Dimension(if any):NA  Shelflife:3 Years  Sterile or Non sterile:Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):Life-o-med</p>
25	<p>Generic Name:IV Cannula Fixator  Model No.:NIL  Intended Use:intended to prevent accidental displacement of intravenous catheters after proper establishment of infusion line access.  Class of medical device:Class A  Material of construction:COTON AND GUM  Dimension(if any):NA  Shelflife:3 Years  Sterile or Non sterile:Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):Life-o-med</p>
26	<p>Generic Name:PAPER TAPE  Model No.:NIL  Intended Use:intended for Healthcare Professionals only.  Class of medical device:Class A  Material of construction:PAPER &amp; GUM  Dimension(if any):NA  Shelflife:3 Years  Sterile or Non sterile:Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):Life-o-med</p>
27	<p>Generic Name:DILATOR  Model No.:NIL  Intended Use:intended for tissue dilation and stimulation of peripheral nerves including spinal nerve roots for location and identification during spinal surgery.  Class of medical device:Class B  Material of construction:PP &amp; DHPE  Dimension(if any):NA  Shelflife:3 Years  Sterile or Non sterile:Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):Life-o-med</p>

28	<p>Generic Name:Scalpel Blade Disposable  Model No.:NIL  Intended Use:intended for use as a cutting device during surgical, pathology and minor medical procedures. It is intended to aid in the protection against accidental injuries during loading, passing, and disposal  Class of medical device:Class B  Material of construction:PP &amp; HDPE  Dimension(if any):NA  Shelflife:3 Years  Sterile or Non sterile:Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):Life-o-med</p>
29	<p>Generic Name:Transparent Film Dressings  Model No.:NIL  Intended Use:" CHG Chlorhexidine Gluconate I.V. Securement Dressing can be used to cover and protect catheter sites and to secure devices to skin. Common applications include securing and covering I.V. catheters, other intravascular catheters and percutaneous devices.  "  Class of medical device:Class B  Material of construction:PVC  Dimension(if any):NA  Shelflife:3 Years  Sterile or Non sterile:Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):Life-o-med</p>
30	<p>Generic Name:TRACHEOTOMY TUBE  Model No.:NIL  Intended Use:The device is intended to be used to provide an artificial airway in order to provide access to the patient's airway for airway management. When inserted in a tracheotomy stoma, the device is secured in place with a neck strap around the patient's neck which is attached to an integral neck plate, thereby providing for a secure artificial airway for spontaneous breathing or direct hook-up to ventilation or anesthesia equipment.  Class of medical device:Class B  Material of construction:PVC  Dimension(if any):NA  Shelflife:3 Years  Sterile or Non sterile:Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):Life-o-med</p>
31	<p>Generic Name:Colostomy Bag  Model No.:NIL  Intended Use:Intended to rest the patient's colon in the case of a temporary procedure, or to act as an artificial outlet for the bowel when the surgery is intended as permanent.  Class of medical device:Class A  Material of construction:PVC  Dimension(if any):NA  Shelflife:3 Years  Sterile or Non sterile:Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):Life-o-med</p>



32	<p>Generic Name:Close Suction Set  Model No.:NIL  Intended Use:intended for endotracheal / tracheostomy suction of adult and pediatric intubated patients (including neonates).  Class of medical device:Class B  Material of construction:PVC  Dimension(if any):NA  Shelflife:3 Years  Sterile or Non sterile:Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):Life-o-med</p>
33	<p>Generic Name:Aspiration Needle  Model No.:NIL  Intended Use:used for aspiration of bone marrow or autologous blood by use of a standard syringe.  Class of medical device:Class B  Material of construction:PVC  Dimension(if any):NA  Shelflife:3 Years  Sterile or Non sterile:Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):Life-o-med</p>
34	<p>Generic Name:Bone Marrow Jamshedi Needle  Model No.:NIL  Intended Use:intended to obtain bone marrow aspirate and core biopsy samples from bone and/or bone marrow.  Class of medical device:Class B  Material of construction:PVC  Dimension(if any):NA  Shelflife:3 Years  Sterile or Non sterile:Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):Life-o-med</p>
35	<p>Generic Name:TRANSURETHRAL OF THE PROSTATE (TUR) SET  Model No.:NIL  Intended Use:Used for endoscopic irrigation during trans-urethral resection of prostate gland.  Class of medical device:Class B  Material of construction:PVC  Dimension(if any):NA  Shelflife:3 Years  Sterile or Non sterile:Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):Life-o-med</p>

Place: GANDHINAGAR

Date:10-Jul-20

State Licensing Authority