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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

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:HIGH PRESSURE MONITORING LINE Model No.:PML-25/PML-50/PML-100/PML-250 - NA Intended Use:channeling a fluid intravenous infusion Treatment Class of medical device:Class B Material of construction:PVC, PC, 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
2	Generic Name:EXTENSION LINE WITH 3 WAY STOP COCK Model No.:EXT-010/EXT-025/EXT-050/EXT-100/EXT-150/EXT-200 - NA Intended Use:Low Pressure Extension Lines used to reduce movement at cannulation site,thereby reducing mechanical irritation & reduces chance of infection. Kink Resistant Tubing with Male Luer lock at one end and 3 way stop cock at the other end for Safe & Secure connection. Class of medical device:Class B Material of construction:PVC, PC, 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:DIAL FLOW REGULATOR Model No.:DFR-001 - NA Intended Use:Controller is intended for use in the intravascular infusion of fluids to be delivered to the patient in a precise manner for no longer than 72 hours. Class of medical device:Class B Material of construction:PVC,PC,HDPE,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>
4	<p>Generic Name:INTRAVENOUS INFUSION SET (I.V. SET) Model No.:IVS-STD/IVS-DEL/IVS-PRE - STANDARD / DELUXE / PREMIUM Intended Use:infusion sets are intended for use in parenteral, enteral and epidural therapies and the administration of fluids, medications, nutritional fluids, Safety features on these devices aid in prevention of needle-stick injuries. Indications for use may include hospital and other medical settings, ambulatory and home use. Class of medical device:Class B Material of construction:PVC, PC, HDPE, 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:BLOOD TRANSFUSION SET (B.T. SET) Model No.:BTS-STD/BTS-DEL/BTS-PRE - STANDARD / DELUXE / PREMIUM Intended Use:Blood Transfusion Set is used to administer blood from a container (plastic bag or glass bottle) to a patient's vascular system through a needle or catheter inserted into a vein. 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>
6	<p>Generic Name:FEEDING TUBE Model No.:FDT-008/FDT-010/FDT-012/FDT-014/FDT-016 - NA Intended Use:Feeding Tube is intended for nasogastric or orogastric delivery of various types of liquid nutritional media through the gastro intestinal tract of neonatal and small pediatric patients, and is not intended for use beyond 30 days. 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>

7	<p>Generic Name:RYLE'S TUBE Model No.:RYT-006/RYT-008/RYT-010/RYT-012/RYT-014/RYT-016 - NA Intended Use:RYLE'S TUBES can be used to remove air and liquids from the stomach (decompression) by connection to intermittent suction units and as temporary feeding tubes; they are used frequently for very ill or comatose patients. ... A tube that is inserted through the nose, down the throat and esophagus, and into the stomach. 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>
8	<p>Generic Name:SUCTION CATHETER Model No.:SUC-008/SUC-010/SUC-012/SUC-014/SUC-016 - NA Intended Use:suction catheters, including closed suction catheters, made of flexible materials and intended for use in suctioning of the respiratory tract. 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>
9	<p>Generic Name:THORACIC CATHETER/CHEST DRAINAGE CATHETER Model No.:THC-008/THC-010/THC-012/THC-014 - NA Intended Use:The catheter is mainly intended for evacuating air and/or liquids from the chest cavity 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>
10	<p>Generic Name:URETHRAL CATHETER Model No.:URC-012/URC-014/URC-016/URC-018 - NA Intended Use:It is used for prolonged urinary drainage, for single use only 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>
1 1	<p>Generic Name:FOLEY CATHETER Model No.:FOC-012/FOC-014/FOC-016/FOC-018/FOC-020/FOC-022 - NA Intended Use:It is used for prolonged urinary drainage Class of medical device:Class B Material of construction:LATEX, SILICON,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>

12	<p>Generic Name:ENDOTRACHEAL TUBE Model No.:ETP-2.5/ETP-003/ETP-3.5/ETP-004/ETP-4.5/ETP-005 - PLAIN AND CUFFED Intended Use:The Endotracheal Tubes are intended for airway management by nasal or oral intubation of the trachea. They are intended for use on Adult and Pediatric patients Class of medical device:Class B Material of construction:PVC, ABS, RUBBER 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>
13	<p>Generic Name:REINFORCED ENDOTRACHEAL TUBE (CUFFED) Model No.:RET-006/RET-6.5/RET-007/RET-7.5/RET-008/RET-8.5/RET-009 - CUFFED Intended Use:The Reinforced Endotracheal Tubes are intended for airway management by nasal or oral intubation of the trachea. They are intended for use on Adult and Pediatric patients Class of medical device:Class B Material of construction:PVC, ABS, RUBBER 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>
14	<p>Generic Name:YANKUR SUCTION SET Model No.:YSS-001 - NA Intended Use:Yankur suction set is intended for suction of the body fluid in combination with aspirator during operation on thoracic cavity or abdominal cavity. Class of medical device:Class B Material of construction:PVC, SILICON, 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>
15	<p>Generic Name:MEASURED VOLUME SET Model No.:MVS-110/MVS-150 - NA Intended Use:MEASURED VOLUME SET indicated for intravenous, intra-arterial, enteral, subcutaneous and epidural infusion of medications or fluids requiring continuous delivery at controlled infusion rates. it is also intended to provide continuous infusion of a local anesthetic directly into the intraoperative site for postoperative pain management Class of medical device:Class B Material of construction:PVC,PC,LD,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>

16	<p>Generic Name: ABDOMINAL DRAINAGE CATHETER AND KIT Model No.: ADK-026/ADK-030/ADK-032 - NA Intended Use: it is use in post operative drainage from abdominal areas Class of medical device: Class B Material of construction: PVC, PP, 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: Urine Collecting Bag with measured Volume Meter Model No.: UMV-001 - NA Intended Use: Urinary cathertisation treatment for urine Collecting Bag with measured Volume Meter Class of medical device: Class A Material of construction: PVC, PP, 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>
18	<p>Generic Name: MUCUS EXTRACTOR Model No.: MUC-001 - NA Intended Use: Mucus Extractor used for aspiration of secretion from the oropharynx in new born babies to ensure free respiration or to obtain mucus specimen for microbiological examination. 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>
19	<p>Generic Name: CORD CLAMP Model No.: CRC-001 - NA Intended Use: The Umbilical cord clamp is used for the clamping of the umbilical cord to prevent bleeding from the cord clamp stump after the cord hard been cut. Class of medical device: Class A Material of construction: 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>
20	<p>Generic Name: GUDAL AIRWAYS Model No.: GDA-000 - NA Intended Use: An oropharyngeal airway is a medical device called an airway adjunct used to maintain or open a patient's airway Class of medical device: Class A Material of construction: PP, 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>

21	<p>Generic Name:SKIN STAPLER Model No.:SKS-035 - NA Intended Use:Staplers are use to close both internal and skin wounds. Skin stapler are usually applied using a disposable stapler and removed with a specialized staple remover Class of medical device:Class B Material of construction:ABS,PP,PVC,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>
22	<p>Generic Name:BLOOD LINE TUBING SET (DIALYSIS TUBING) Model No.:BTD-001 - NA Intended Use:Hemodialysis blood tubing with attached priming set and trasducer protectores is a singal use disposable arterial and venus bloodline set intended to provide extracorporal acces during hemodialysis. Class of medical device:Class B Material of construction:PP,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</p>
23	<p>Generic Name:A V FISTULA NEEDLE Model No.:AVF-015/AVF-016/AVF-017 - NA Intended Use:Use for temporary cannulation for vascular access for extracorporeal blood treatment. This device is intended to single use only and is for temporary catheterization less than 30 days. The safety feature (foldable wing and Wing Eater) aids in prevention of needlestick injury when removing and discarding needle after dialysis session. Class of medical device:Class B Material of construction:PP,PVC,HDPE,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>
24	<p>Generic Name:INTRODUCER NEEDLE Model No.:INN-016/INN-018/INN-020 - NA Intended Use:Accessing a blood vessel for placement of a guide wire into circulatory system Class of medical device:Class B Material of construction:PVC,HDPE,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>

25	<p>Generic Name:SPINAL NEEDLE Model No.:SPN-018/SPN-019/SPN-020/SPN-021/SPN-022/SPN-023/SPN-024/SPN-025/SPN-026/SPN-027 - NA Intended Use:spinal needles with or without introducer are intended for the injection of local anesthetics into the subarachnoid space to provide spinal anesthesia for pain management or to facilitate CSF sample collection for diagnostic purposes (lumbar puncture). The needles are intended for use in any target population with consideration given to the anatomy of the patient. Class of medical device:Class B Material of construction:PVC,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>
26	<p>Generic Name:SINGLE LUMEN DIALYSIS KIT Model No.:SLK-014 - NA Intended Use:it is indicated for use in attaining short-term or longterm vascular access for hemodialysis, hemoperfusion or apheresis therapy. Access is attained via the internal jugular vein, external jugular vein, subclavian vein, or femoral vein. Class of medical device:Class B Material of construction:PVC,PP,SS,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>
27	<p>Generic Name:GUIDE WIRE Model No.:GWS-18150/GWS-25150/GWS-32150/GWS-35150/GWS-38150/GWJ-32150/GWJ-35150/GWJ-38150 - NA Intended Use:guide wires that are used for the introduction and plasment of dignostic and placement of dignostic or interventional devices in the coronary and peripleral vasculature and many be used to reach and cross a target lesion. Class of medical device:Class A Material of construction:PP,SS,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>
28	<p>Generic Name:BOUGIE Model No.:BOG-001 - NA Intended Use:it is 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: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>

29	<p>Generic Name:CLOSE SUCTION SET (MINI VAC SET) Model No.:CSS - NA Intended Use:it is designed to correct to the endotracheal tube or tracheotomy tube of the patient and remains in place up to 48 hours Must be relapse after 24 hours while the angled connector (elbow) may be replaced. Class of medical device:Class B Material of construction:PVC,HDPE,SS,LD 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:MOUNT CATHETER Model No.:CME/CMS - NA Intended Use:it is connected between the patient and the breathing systems the mount catheter with double swivel connector and flexible tubing provide mobility and flexibility to the patient end of the circuit. The catheter mount is used as an intermediary connection between the patient and the breathing system. Class of medical device:Class B Material of construction:PVC,HDPE,SS,ABS,LD 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:SURGICAL GLOVES (EXAMINATION GLOVES) Model No.:SUG - NA Intended Use:The examination gloves is a disposable devices use for medical and dental purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. Class of medical device:Class B Material of construction:RUBBER 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:FEMORAL CATHETER Model No.:FMC-014 - NA Intended Use:It is use to drain central venous blood via the femoral vein during extra corporeal procedures for up to six hours. Class of medical device:Class B Material of construction:PP,PU,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</p>

33	<p>Generic Name:INTRAVENOUS CANNULA (I.V. CANNULA) Model No.:IVC-014/IVC-016/IVC-018/IVC-020/IVC-022/IVC-024 - NA Intended Use:it is inserted into an artery commonly the radial artery and is used during major operations and in critical care areas to measure beat to beat blood pressure and to draw repeated blood sample. Class of medical device:Class B Material of construction:PP,PU,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:BIOPSY GUN Model No.:BIP - NA Intended Use:The core needle biopsy devices is intended for use in obtaining biopsies from soft tissues such as liver kidney breast prostate spleen. Class of medical device:Class B Material of construction:PP,SILICON,PVC,PC,HDPE,ABS,COTAN 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:EPIDURAL CATHETER KIT Model No.:EPK-016/EPK-018 - NA Intended Use:The Epidural catheter kit is use up to 72 hours the proposed flat anesthesia conduction filter is substantially equivalent to the predicate devices with respect to indications for use. Class of medical device:Class B Material of construction:PP,SILICON,PVC,PC,HDPE,ABS,COTAN 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>
36	<p>Generic Name:PCN CATHETER Model No.:PCN-008/PCN-010/PCN-012 - NA Intended Use:The Precancerous nephrostomy (PCN) catheter with needle is used in same cases as the pcn catheter. it can however directly puncture through the skin in to the kidney the needle is made of stainless steel. Class of medical device:Class B Material of construction:PP,SS,LD,PVC,PU,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>

37	<p>Generic Name:PIGTAIL CATHETER Model No.:PGC-008/PGC-010/PGC-012 - NA Intended Use:it is intended for use in angiographic procedures it delivers radio opaque media and therapeutic agents to selected sites in the vascular system Class of medical device:Class B Material of construction:PVC,PU,LD,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>
38	<p>Generic Name:FOGATI CATHETER Model No.:FGC-005/FGC-006/FGC-007 - NA Intended Use:it is intended to be used for temporary occlusion in the peripheral vascular system. Class of medical device:Class B Material of construction:PP,PVC,SS,ABS,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>
39	<p>Generic Name:NEPHROSTOMY CATHETER KIT Model No.:NPK - NA Intended Use:It is intended for use in angiographic procedures. It delivers radiopaque media and therapeutic agents to selected sites in the vascular system. 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>
40	<p>Generic Name:HEMODIALYSIS CATHETER KIT Model No.:DLS-024/DLS-028/DLS-036/DLC-024 - NA Intended Use:Hemodialysis Catheter is indicated for use in attaining Long-Term vascular access for Hemodialysis . It may be inserted percutaneously and is primarily placed in the internal jugular vein of an adult patient. This catheter is indicated for > 30 days long term placement. The catheter inserted on the pigtail catheter can be used to straighten the catheter tip for easier insertion into the sheath. Class of medical device:Class B Material of construction:PVC,PP,SS,HDPE,PU 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>

41	<p>Generic Name:CODAN SET Model No.:CDS-001 - NA Intended Use:Hydrophobic End Cap for Universal Use; Reduces Risk of Bacterial or Particulate Contamination; Safe and Leak Free Priming of Sets; Bacteria-Free, Drip-Free Class of medical device:Class B Material of construction:NA 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>
42	<p>Generic Name:TRANSDUCER PROTECTOR Model No.:TNP-001 - NA Intended Use:Transducer protectors are used in hemodialysis blood lines to keep the blood side of the circuit separated from the machine side, and to prevent contamination of the machine by the blood flowing through the circuit.Transducer protectors let air pass while preventing the blood from passing through. Class of medical device:Class B 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</p>
43	<p>Generic Name:ICD BAG Model No.:CD-1000/ICD-2000 - NA Intended Use:The ICD bag provides under water seal drainage system. It is used for the collection of fluid or to drain air from the thoracic cavity. 1000 ml Capacity bag graduated at 50 ml Specially molded handle with provision to hang the bag 100 cms long tube has connector to connect to the ICD tube. The soft and kink resistant tube has blocker which can be used to block the tube while emptying the bag.it is use when Cardiovascular Surgery Class of medical device:Class B 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</p>

Place: Gandhinagar

Date 29-May-19

State Licensing Authority