

## FORM MD-9

[See sub-rule (1) rule 25]

Licence to Manufacture for Sale or for Distribution of Class C or Class D medical device

Licence Number: MFG/MD/2019/000132

- 1. M/s Life O Line Technologist, Plot NO. 864/1 Paiki, Nr. IOCL Petrol Pump, Ahmedabad-Mehmedabad RoadPO 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. The names, qualifications and experience of the competent technical staff responsible for the manufacture and testing of the above mentioned medical device(s): As per records maintain by the manufacturer
- 4. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

## ) S (ANNEXURE ( ) S

S.No.	Details Of Device(s)
1	Generic Name:DOUBLE LUMEN DIALYSIS KIT : JUGULAR / STRAIGHT
	Model No.:DLC-1213/DLC-1215/DLS-1215/DLS-1220 - NA
	Intended Use:The intended use of the Short-Term Dialysis Catheter attaining temporary/Short-
	Term (less than 30 days) vascular access for dialysis
	Class of medical device:Class C
	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
2	Generic Name:TRIPLE LUMEN DIALYSIS KIT
	Model No.:TLC-1213/TLS-1215 - NA
	Intended Use:The third lumen is completely independent from the two dialysis lumens and is
	indicated for power injection of contrast media central venous pressure monitoring and can be used
	for blood draws and fluid or medication delivery without the need for a separate access.
	Class of medical device:Class C
	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

Generic Name: D.J. STANT 3 Model No.:DJO-526/DJO-626/DJC-526/DJC-626 - NA Intended Use: D.J stent is intended to facilitated the temporary internal drainage of urine from the kidney to the bladder via placement endoscopically by a trained physician. Class of medical device: Class C Material of construction:PP.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 Generic Name: Disposable Electrosurgical Cautery Pencil 4 Model No.:CTP-001 - NA Intended Use: The pencil can be used during electrosurgical procedures for both cutting and coagulation. Device Description: Electrcsurgery can be used to accomplish any one of three functions in the surgical environment: incise, desiccate, or coagulate. This is a single use, disposable device. Class of medical device: Class C Material of construction:PVC,HDPE,SS ABS,COPPER 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 Generic Name: CVC CATHETER (CENTRAL VENUS CATHETER) - S.L. / D.L. / T.L. 5 Model No.:SCVC-1615/DCVC-715/TCVC-715 - NA Intended Use: Central venous catheter is a polyurethane than C.V.C with is intended to insert it to the patient's vascular system for short term use. (less then 30 days) to sample blood monitor blood pressure or administer fluid intravenously. Class of medical device: Class C Material of construction:PVC,HDPE,SS ABS,COPPER,PP सत्यमेव जयते 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

Place:

Date 26-Jul-19

Central Licensing Authority