



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/2020/000124

1. M/s ALPHA THERAPEUTICS PVT LTD, 869 1 Village RAJODA Near Karnavati Hotel Sarkhej Bavla Highway Tal Bavla Dist Ahmedabad 382 220BAVLA, Gandhinagar, Gujarat (India) - 382220 Telephone No.: 9376809552 FAX: 9376809552 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s ALPHA THERAPEUTICS PVT LTD, 869/1 RAJODA, SARKHEJ-BAVLA ROAD,, Ahmedabad, Gujarat (India) - 382220 Telephone No.: 9374073644 FAX: 9374073644

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: Sterile Disposable Infusion Set with/without air vent BIS 12655 For Single Use Only Model No.: NIL Intended Use: Transfusion Set is used to administer blood/drugs 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, SS 316 L Dimension(if any): AS PER BIS 12655 Shelflife: 36 MONTHS Sterile or Non sterile: Sterilized Brand Name(if registered under the Trade Marks Act, 1999): ATPL NANO</p>
2	<p>Generic Name: Sterile Disposable Blood Administration Set WITH/without air vent BIS 9824 For Single Use Only Model No.: NIL Intended Use: Transfusion Set is used to administer blood/drugs 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, SS 316 L Dimension(if any): AS PER BIS 9824 Shelflife: 36 MONTHS Sterile or Non sterile: Sterilized Brand Name(if registered under the Trade Marks Act, 1999): ATPL BT</p>

3	<p>Generic Name: Sterile Disposable Measured Volume Intravenous Infusion Set without Air Vent BIS 12655 For single use only</p> <p>Model No.: NIL</p> <p>Intended Use: It is intended for use in the administration of fluids from a container into the patient's vascular system through a vascular access device.</p> <p>Class of medical device: Class B</p> <p>Material of construction: PVC, SS 316 L</p> <p>Dimension(if any): AS PER BIS 12655</p> <p>Shelflife: 36 MONTHS</p> <p>Sterile or Non sterile: Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999): NEODRIP</p>
4	<p>Generic Name: Disposable Sterile Dial Flow Regulator with or without infusion set for Single Use Only</p> <p>Model No.: NIL</p> <p>Intended Use: An IV system and administration device offering precision care and consistent delivery.</p> <p>Class of medical device: Class B</p> <p>Material of construction: PVC</p> <p>Dimension(if any): AS PER STANDARD</p> <p>Shelflife: 36 MONTHS</p> <p>Sterile or Non sterile: Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999): ACCUFLUX</p>
5	<p>Generic Name: Sterile Disposable Three Way Stop Cock With/without Extension Tube For single use only</p> <p>Model No.: NIL</p> <p>Intended Use: It is indicated for fluid flow directional control and for providing access port for administration of solution, withdrawal of fluid and pressure monitoring</p> <p>Class of medical device: Class A</p> <p>Material of construction: PVC, PC, HDPE</p> <p>Dimension(if any): AS PER STANDARD</p> <p>Shelflife: 36 MONTHS</p> <p>Sterile or Non sterile: Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999): ATPL XT</p>
6	<p>Generic Name: Sterile Disposable High Pressure Monitoring Line for Single Use Only</p> <p>Model No.: NIL</p> <p>Intended Use: Extension sets are sterile devices for single use only. They are intended to be used as part of a system for the infusion of fluids/medications in medical applications.</p> <p>Class of medical device: Class B</p> <p>Material of construction: PVC</p> <p>Dimension(if any): AS PER STANDARD</p> <p>Shelflife: 36 MONTHS</p> <p>Sterile or Non sterile: Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999): ATPL HPM</p>

7	<p>Generic Name: Sterile Tracheobronchial Suction Catheter For Single Use Only Model No.: NIL Intended Use: Clearing the airways of mucus, pus, or aspirated materials to improve oxygenation and ventilation. Class of medical device: Class B Material of construction: PVC Dimension(if any): AS PER STANDARD Shelflife: 36 MONTHS Sterile or Non sterile: Sterilized Brand Name(if registered under the Trade Marks Act, 1999): ATPL MX</p>
8	<p>Generic Name: Sterile Tracheobronchial Suction Catheter For Single Use Only Model No.: NIL Intended Use: Suction Catheters feature a whistle tip and a thumb control port for precise and accurate suctioning. Class of medical device: Class B Material of construction: PVC Dimension(if any): AS PER STANDARD Shelflife: 36 MONTHS Sterile or Non sterile: Sterilized Brand Name(if registered under the Trade Marks Act, 1999): ATPL SUCC</p>
9	<p>Generic Name: Sterile Urethral/ Nelaton Catheter (Plain & Thumb Control) For Single Use Only Model No.: NIL Intended Use: A long small gauge catheter designed for insertion directly into a ureter either through the urethra and bladder or posteriorly via the kidney. Class of medical device: Class B Material of construction: PVC Dimension(if any): AS PER STANDARD Shelflife: 36 MONTHS Sterile or Non sterile: Sterilized Brand Name(if registered under the Trade Marks Act, 1999): ATPL U-CATH</p>
10	<p>Generic Name: Sterile Infant Feeding Tube For Single Use Only Model No.: NIL Intended Use: A feeding tube is a device that's inserted into your stomach through your abdomen. It's used to supply nutrition when you have trouble eating Class of medical device: Class B Material of construction: PVC Dimension(if any): AS PER STANDARD Shelflife: 36 MONTHS Sterile or Non sterile: Sterilized Brand Name(if registered under the Trade Marks Act, 1999): ATPL FT</p>
1 1	<p>Generic Name: Sterile Disposable Nasogastric/RYLE'S Tube For Single Use Only Model No.: NIL Intended Use: It is a special tube that carries food and medicine to the stomach through the nose. It can be used for all feedings or for giving a person extra calories. Class of medical device: Class B Material of construction: PVC Dimension(if any): AS PER STANDARD Shelflife: 36 MONTHS Sterile or Non sterile: Sterilized Brand Name(if registered under the Trade Marks Act, 1999): ATPL RT</p>

12	<p>Generic Name: Sterile Disposable Scalp Vein Set For Single Use Only Model No.: NIL Intended Use: Intended to be used for insertion into the patient's vascular system (single use only) as an in-dwelling device to administer fluids intravenously or to sample blood Class of medical device: Class B Material of construction: PVC, SS 316 L Dimension(if any): AS PER STANDARD Shelflife: 36 MONTHS Sterile or Non sterile: Sterilized Brand Name(if registered under the Trade Marks Act, 1999): VENOLOK</p>
13	<p>Generic Name: Sterile Disposable Umbilical occlusion device For Single Use Only Model No.: NIL Intended Use: These devices may be a clip, tie, tape, or other article used to close the blood vessels in the umbilical cord of a newborn infant. Class of medical device: Class A Material of construction: PP Dimension(if any): AS PER STANDARD Shelflife: 36 MONTHS Sterile or Non sterile: Sterilized Brand Name(if registered under the Trade Marks Act, 1999): CLAMPY</p>
14	<p>Generic Name: Non Sterile I.V. Cannula Fixator for Single Use Only Model No.: NIL Intended Use: Dressing aerosol, non-adherent, dressing, periodontal, kit, dressing pad, dressing. Class of medical device: Class A Material of construction: WOOLEN CLOTH Dimension(if any): AS PER STANDARD Shelflife: NIL Sterile or Non sterile: Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999): TEFLOFIX</p>
15	<p>Generic Name: Sterile Disposable Intra venous Cannulae For Single Use only Model No.: NIL Intended Use: The IV Cannula is a passive device to provide for the infusion of fluids, drugs, and/or blood components, or to facilitate the placement of Vascular Access devices . Class of medical device: Class B Material of construction: PVC, SS 316 L Dimension(if any): SIZES : FG 16G, 18G, 20G, 22G, 24G, 26G Shelflife: 36 MONTHS Sterile or Non sterile: Sterilized Brand Name(if registered under the Trade Marks Act, 1999): TEFLO</p>

Place: GANDHINAGAR

Date: 02-Jun-20

State Licensing Authority