



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/2021/000327

Endorsement No. 1

1. M/s Medihub Sciencetec Private Limited, Plot No 4, NH - 7, MMDA Industrial Estate, Maraimalai Nagar, Chengalpattu, Kanchipuram, Tamil Nadu (India) - 603209 Telephone No.: 7338957485, 9600055935, 8870644041, FAX: 04447400484 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s Medihub Sciencetec Private Limited, Plot No 4, NH - 7, MMDA Industrial Estate, Maraimalai Nagar, Kanchipuram, Tamil Nadu (India) - 603209 Telephone No.: 044-47400478, 044-47400478, 9600055935, 7338957485 FAX: 044-47400484

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	Generic Name:Cardiopulmonary bypass heat exchanger (Myocardial Protection System) Model No.:M8CP / 06/2020 / Cardioplegia delivery system - Capacity - 2 Liters ,M20MP /06/2020 /MYOCARDIAL PROTECTION SYSTEM WITH DELIVERY SET - Delivery set -75 inches ,1/4 1 feet ,M25MP /06/2020 / MYOCARDIAL PROTECTION SYSTEM WITHOUT DELIVERY SET UNSTERILE - Device Prime Volume - 40ml, Blood-- Inlet - 1/4" ,Outlet-1/4" , Water -- Inlet - 1/2",Outlet-1/2"NON STERILE,M23MP /06/2020 /MYOCARDIAL PROTECTION SYSTEM WITH DELIVERY SET (Delnido) - Delnido circuit ,M17MP /06/2020 /MYOCARDIAL PROTECTION SYSTEM WITHOUT DELIVERY SET - Device Prime Volume - 40ml, Blood-- Inlet - 1/4",Outlet-1/4" ,Water -- Inlet - 1/2" ,Outlet-1/2",M16MP /06/2020 / MYOCARDIAL PROTECTION SYSTEM WITH DELIVERY SET -Peadatric - Delivery set - 200 cm tubing 1 feet ,M22MP /06/2020 /MYOCARDIAL PROTECTION SYSTEM WITH DELIVERY SET - Delivery set -95 inches 1/4 tubing,1 feet 1/4 tubing,White Pinch clamp ,M15MP /06/2020 /MYOCARDIAL PROTECTION SYSTEM WITH DELIVERY SET ADULT - Delivery set - 95 inches 1/4 tubing 1 feet 1/4 tubing ,M24MP /06/2020 /MYOCARDIAL PROTECTION SYSTEM WITH DELIVERY SET (Delnido) - Delivery set - 95 inches 1/4 tubing,1 feet 1/4 tubing, Gray Pinch clamp Intended Use:Myocardial Protection System is a non-invasive device, intended for short term use consisting of a heat exchange system used in extra-corporeal circulation to warm or cool the blood or perfusion fluid flowing through the device. It is used to stop the beating of heart and to preserve the myocardium cells during Open-heart surgery (6 hours). Class of medical device:Class B Material of construction:1.Heat Exchanger Shell & integrated connectors- Poly carbonate Poly Carbonate Clear -Resin Code : Lexan 144R,164R / Equivalent; 2.Top & Bottom cover - Poly carbonate white- Resin Code : Lexan 144R,164R / Equivalent;3. Heat Exchanger tubes- Anodised Aluminium Alloy temper 63400(HV90WP); 4.Connecting tubes Purgelines -PVC- Non Toxic Medical Grade Dimension(if any):40ml -Priming capacity. Shelflife:36 months / 3 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SPICTRA
2	Generic Name:Cardiopulmonary bypass cardiotomy suction line blood filter (Cardiotomy Reservoir) ISO 15674 Model No.:M7C / 06/2020 / CARDIOTOMY RESERVOIR ADULT - Capacity - 2 Liters ,M4C / 06/2020 / CARDIOTOMY RESERVOIR - Capacity -3 Liters Intended Use:Cardiotomy reservoir is a device used as part of a gas exchange (oxygenator) system to filter nonbiologic particles and emboli (a blood clot or a piece of foreign material flowing in the bloodstream which will obstruct circulation by blocking a vessel) out of the blood. This device is intended for use in the cardiotomy suction line during cardiopulmonary bypass surgery (6 Hours) Class of medical device:Class B Material of construction:1. Shell: Polystyrene -Resin Code: SC 206; 2.Top plate/Middle plate - High Impact Poly Styrene (HIPS) - Resin Code: SH 731 / Equivalent, 3.Pre-filters (2mm soft mesh & Net) - High Density Polyethylene (HDPE); 4.Depth Filter Pad- 40micron Polyester; 5. Filter bottom cover – HIPS; 6. Inlet 1/4" and outlet /3/8" connectors – HIPS. 7. Coarse Filter – 200micron Polyester. Dimension(if any):Volume - 2 / 3 liters capacity Shelflife:36 months / 3 Years Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):SPICTRA

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3	Generic Name: Vacuum-powered body fluid suction apparatus (Chest / Thoracic Drainage System) Model No.: M3D / 06/2020 / Chest / Thoracic Drain System M3D - Capacity - 2lts; Single Chamber; Drain -4 ft; Vacuum -0.3ft; Ports -Vacuum - 1; Drain - 1; Fill/Vent-.1 ,M5D / 06/2020 / Chest / Thoracic Drain System M5D - Capacity - 2lts; Single Chamber; Drain -4 ft; Vacuum -3 ft; Ports -Vacuum - 1; Drain - 1; Fill/Vent-.1 ,M6D / 06/2020 / Chest / Thoracic Drain System M6D - Capacity - 2lts; Single Chamber; Drain -5 ft; Vacuum -2ft; Ports -Vacuum - 1; Drain - 1; Fill/Vent-.1 ,M8D / 06/2020 / Chest / Thoracic Drain System M8D - Capacity - 2lts; Single Chamber; Drain -5 ft; Vacuum -2ft; Ports -Vacuum - 1; Drain - 1; Fill/Vent-.1 ,M14D / 06/2020 / Chest / Thoracic Drain System M14D - Capacity - 2lts; Single Chamber; Drain -6.5 ft; Vacuum -2ft; Ports -Vacuum - 1; Drain - 1; Fill/Vent-.1 Intended Use: Chest / Thoracic Drainage System and its Accessory Bedside Vacuum Controller is closed system working under regulated vacuum to collect the intra pleural drainage after cardio pulmonary or thoracic surgery. This product is used to collect the wounded blood from the chest cavity after closing the sternum. Class of medical device: Class B Material of construction: 1. Shell - Polystyrene -Resin Code: SC 206; 2. Top plate – Poly Carbonate (PC) White- Resin Code: Lexan 144R – 3. Overflow sheet - High impact polystyrene- Resin Code: SH 731 / Equivalent; Vacuum connector – ¼” – Polypropylene-Resin Code: 110 MA. 4. Drain tube – Medical grade PVC. 5. Patient end & Vacuum line – PVC soft Translucent, Hardness 50-55 SH. Dimension(if any): 2 liter capacity Shelflife: 36 months / 3 Years Sterile or Non sterile: Sterilized Brand Name(if registered under the Trade Marks Act, 1999): SPICTRA
4	Generic Name: Closed wound drainage tube (Chest drain catheter) ISO 20697 Model No.: M6CDC/ 06/2020 / Adult - French size - FG 34 ,M9CDC/ 06/2020 / Paediatric - French size - FG 14 ,M10CDC/ 06/2020 / Paediatric - French size - FG 16 ,M14CDC/ 06/2020 / Paediatric - French size - FG 22 ,M7CDC/ 06/2020 / Adult - French size - FG 36 ,M8CDC/ 06/2020 / Paediatric - French size - FG 12 ,M2CDC/ 06/2020 / Adult - French size - FG 26 , M12CDC/ 06/2020 / Paediatric - French size - FG 18 ,M1CDC/ 06/2020 / Adult - French size - FG 24 ,M4CDC/ 06/2020 / Adult - French size - FG 30 ,M5CDC/ 06/2020 / Adult - French size - FG 32 ,M3CDC/ 06/2020 / Adult - French size - FG 28 ,M13CDC/ 06/2020 / Paediatric - French size - FG 20 Intended Use: Closed Wound drainage tube or system (Chest / Thoracic drainage Catheter) is intended to be use for post-operative drainage / evacuation of air or fluid from pleural space Class of medical device: Class B Material of construction: 1. Catheter tubes – Medical grade Polyvinyl chloride; 2. Multibarbed Connectors – Polypropylene; 3. Plug – Soft PVC Dimension(if any): Length - 45cm Shelflife: 36 months / 3 Years Sterile or Non sterile: Sterilized Brand Name(if registered under the Trade Marks Act, 1999): SPICTRA

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5	Generic Name:Cardiopulmonary bypass vascular tubing (ISO 15676) Model No.:1/4 PVC Tubing (180 meter) - Unsterile tubing ,3/8 PVC Tubing (75 meter) - Unsterile tubing ,1/2 PVC Tubing (45meter) - Unsterile tubing ,1/4 PVC Tubing (12 Feet) - Diameter - 1/4 inch, Length - 12 feet, sterile,3/8 PVC Tubing (10 Feet) - Diameter - 3/8 inch, Length - 10 feet, sterile,1/2 PVC Tubing (10 Feet) - Unsterile tubing, Length - 10 feet, sterile Intended Use:Cardiopulmonary bypass vascular tubing is a device used in cardiopulmonary surgery to interconnect the catheters and cannulas with an oxygenator.The device includes accessory bypass equipment. It is a non-invasive device, intended for short term use. Class of medical device:Class B Material of construction:Tubing – Medical grade Poly vinyl chloride Dimension(if any):1/4 inch X 12 feet; 1/2 inch X 10 feet; & 3/8 inch X 10 feet. Shelflife:36 months / 3 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SPICTRA
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Place:

Date28-Dec-22

State Licensing Authority

