



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/2021/000327

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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K
SIVABALAN

Digitally signed by K SIVABALAN
DN: c=IN, o=DIRECTORATE OF
DRUGS CONTROL,
ou=DIRECTORATE OF DRUGS
CONTROL ADMINISTRATION
TAMILNADU, postalCode=600006,
st=TAMIL NADU, cn=K SIVABALAN
Date: 2021.09.30 16:29:02 +05'30'

1	Generic Name:closed suction system (ISO 8836) Model No.:NIL Intended Use:Closed Suction System is intended for endotracheal suctioning to provide a patient airway by removing excess fluids, secretions, exudates and transudate through the artificial airway. Class of medical device:Class B Material of construction:Closed Suction Catheter manifold(Isolation Chamber)- Poly Carbonate, Isolation Chamber Knob - Acrylonitrile butadiene styrene, Patient Connection Port (22 mm double swivel adapter) - Poly Propylene, Machine end of the Closed Suction Catheter Manifold(15 mm double swivel adapter- Poly Propylene,15 mm corrugated tube-Low Density Polyethylene,15 X 22 mm Adapter-Poly Propylene),Flushing line with cap(Injection Port Cap line)-Poly Vinyl Chloride,Bush Bottom-Poly Propylene,Silicone Bush-Silicone,Protective Sleeve (Protective PE Cover)-Low Density Poly Propylene,Shaft of the Suction Catheter (Suction Catheter)-Poly Vinyl Chloride,Printing on the shaft of Suction Catheter(Suction Catheter)- medical grade ink, Bush Top-Poly Propylene,Suction Catheter connector(Thumb control valve Body)-Acrylonitrile butadiene styrene, Suction Control Device (Thumb control valve Body-Acrylonitrile butadiene styrene,Thumb control valve-Nitrile Rubber,Thumb control valve Ring-Acrylonitrile butadiene styrene,SS Spring-Stainless Steel),ProtectiveCap (¼ inch Suction port Cap)-Poly Vinyl Chloride Dimension(if any):1.33 mm (4 F) x 650 mm,1.5 mm (4.5 F) x 650 mm,1.67 mm (5 F) x 650 mm,2 mm (6 F) x 650 mm,2.1 mm (6.5 F) x 650 mm,2.33 mm (7 F) x 650 mm,2.5 mm (7.5 F) x 650 mm,2.67 mm (8 F) x 650 mm,3 mm (9 F) x 650 mm,3.33 mm (10 F) x 650 mm,4 mm (12 F) x 650 mm,4.67 mm (14 F) x 650 mm,5 mm (15 F) x 650 mm,5.33 mm (16 F) x 650 mm,6 mm (18 F) x 650 mm,6.67 mm (20 F) x 650 mm. Shelflife:3 years Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):SPICTRA
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Place:

Date30-Sep-21

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SIVABALA
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NADU, cn=K SIVABALAN
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State Licensing Authority