



सत्यमेव जयते

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/2022/000710**

Endorsement No. **2**

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. 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.

ANNEXURE

S.No.	Details Of Device(s)
1	Generic Name: Arterial Line Blood Filter Model No.: M5AF / 06/2020 - Arterial Blood filter with loop - Adult with loop, M6AF / 06/2020 - Arterial Blood filter without loop - Adult without loop Intended Use: Arterial line Blood filter (ABF) is used for removal of air micro aggregates, surgical debris & particles, without any damage to the blood components. This is a single-use device Class of medical device: Class C Material of construction: Filter - Polyester; Filter frame - Polypropylene; Base holder- ABS; Housing - Polycarbonate; Dimension(if any): Diameter - 6.5cm ; Length - 18cm; Shelflife: 36 months / 3 Years Sterile or Non sterile: Sterilized Brand Name(if registered under the Trade Marks Act, 1999): SPICTRA
2	Generic Name: Cardio pulmonary bypass defoamer Model No.: M7AB / 06/2020 - Bubble Trap Adult With loop - Adult with loop , M8AB / 06/2020 - Bubble Trap Adult Without loop - Adult without loop , M6PB / 06/2020 - Bubble trap Paediatrics with loop - Paediatrics with loop , M7PB / 06/2020 - Bubble trap Paediatrics without loop - Paediatrics without loop , M5IB / 06/2020 - Infant Bubble trap - Infant Bubble trap , M6AB / 06/2020- Bubble Trap Adult Low prime - Adult Low prime Intended Use: It is a non-invasive device, intended for short term use (not more than 30 days). It is use to trap the air emboli's before entering into the circulatory system Class of medical device: Class C Material of construction: Filter - Polyester; Filter frame - Polypropylene; Base holder- ABS; Housing - Polycarbonate; Dimension(if any): Capacity - 200ml/120ml/25ml Shelflife: 36 months / 3 Years Sterile or Non sterile: Sterilized Brand Name(if registered under the Trade Marks Act, 1999): SPICTRA

RAJEEV SINGH
RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
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Place:

Date 08-Jul-24

Central Licensing Authority

