



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. 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. 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:Hemoconcentrator set (Haemoconcentrator) Model No.:M4HC / 06/2020 /0.3 Sq.m surface area for Pediatrics/ Infant - Surface Area - 0.3 square meter ,M5HC / 06/2020 /0.7 Sq.m surface area for Adult - Surface Area - 0.7 square meter Intended Use:Haemoconcentrators are devices used during open heart surgery for the selective separation of water and fluids from blood using a semi permeable ultra-filtration membrane in order to increase the Hematocrit of blood. Class of medical device:Class C Material of construction:Filter - Polyethersulfone; Housing - Polycarbonate; blood and drain lines - Polyvinyl chloride; Potting material - Polyurethane. Dimension(if any):Diameter - 6.5cm ; Length - for 0.3 sq.m - 12cm; for 0.7sq.m - 21cm Shelflife:36 months / 3 Years Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):SPICTRA

Place:

Date01-Jun-23

RAJEEV SINGH
RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL
ORGANIZATION, ou=RAJEEV SINGH RAGHUVANSHI,
1015a0654fec7754b765db1cb, postalCode=600034,
st=TAMIL NADU,
serialNumber=657F5E47D940985D8F03BDC902D0E1F
E73CFA12A1A126EA94FA5701124A19013, cn=RAJEEV
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