

**Duplicate licence**

**LA No: 108/KPM/2017**

**FORM 20B**  
**[See Rule 61 (1)]**

***LICENCE TO SELL, STOCK OR EXHIBIT [OR OFFER] FOR SALE, OR DISTRIBUTE BY WHOLESALE, DRUGS OTHER THAN THOSE SPECIFIED IN [SCHEDULES C, C(1) AND X]***

1. M/s. Medihub Sciencetec Private Limited is hereby licensed to sell, stock or exhibit or offer for sale or distribute by wholesale drugs other than those specified in Schedules C, C(1) and X on the premises situated at Room No:2, Ground Floor, FG Store, P. No: 4, NH7, Industrial Area – 11 (CMDA), Tamilnadu, Maraimalai Nagar – 603 209 subject to the conditions specified below and to the provisions of the Drugs and Cosmetics Act, 1940, and the Rules thereunder.

2. The Licence shall be force from 20.04.2017 to 19.04.2022

3. The sale shall be made under the personal supervision of a competent person:  
**Thiru. K. Ramesh – 43152/A2**

4. Categories of Drugs.: *All Drugs other than those specified in Schedule C, C(1) and X of Drugs and Cosmetics Rules, 1945.*

**Licence No. 667/KPM/20B**  
**Date: 20.04.2017**

**Signed xxxxxx**  
**Licensing Authority**  
**Assistant Director of Drugs Control**  
**Kanchipuram Zone, Chennai.6**

  
**Licensing Authority**  
**Assistant Director of Drugs Control**  
**Kanchipuram Zone, Chennai.6**



**Duplicate licence**

**LA No: 108/KPM/2017**

**FORM 21-B**

[See Rule 61 (2)]

*Licence to sell, stock or exhibit [or offer] for sale, or distribute by wholesale drugs specified in Schedules C and C (1) [excluding those specified in Schedule X]*

1. **M/s. Medihub Sciencetec Private Limited** is hereby licensed to sell, stock or exhibit [or offer] for sale, or distribute by wholesale on the premises situated at **Room No:2, Ground Floor, FG Store, P. No: 4, NH7, Industrial Area – 11 (CMDA), Tamilnadu, Maraimalai Nagar – 603 209** the following categories of drugs specified in Schedule C and C (1) [excluding those specified in Schedule X] to the Drugs and Cosmetics Rules, 1945.

2. The Licence shall be force from **20.04.2017 to 19.04.2022**

3. The sale shall be made under the personal supervision of a competent person :

**Thiru. K. Ramesh – 43152/A2**


4. *Categories of drugs: All Drugs specified in Schedule C, C(1) ( excluding those specified in Schedule X) of Drugs and Cosmetics Rules, 1945.*

This licence is subject to the conditions stated below and to the provisions of the Drugs and Cosmetics Act, 1940, and the Rules thereunder.

**Licence No. 659/KPM/21B**

**Date: 20.04.2017**

Signed xxxxxx  
Licensing Authority  
Assistant Director of Drugs Control  
Kanchipuram Zone, Chennai.6

  
Licensing Authority  
Assistant Director of Drugs Control  
Kanchipuram Zone, Chennai.6



# Government of Tamil Nadu

E-Challan

Payable at - STO Tambaram

Remitter Copy



**Challan Number** 20220412003586 **Challan Date** 12-Apr-2022 **Payment Date**

**Remitter Type** Public **Remitter Code** 30 **Remitter Name** ELUMALAI

**Mobile No.** 9500026170 **Aadhaar No.** **Remitter Address** NH7

**Department** 01906-Tamil Nadu Food Safety and Drug Administration Department **District** CHENGALPATTU **DDO Code** 35060015

**DDO / Office Name** NA **Department Transaction ID** **Office Name**

Receipt Type	Sub Type	Acct Code	Amount	Reference No.	Remark
Sales Services - Allopathic Drugs	Application for Payment of retention fees for Licence of Allopathic drugs(Sales)	021004104AA22722	3000	667/KPM/20B, 659/KPM/21B	M/S. MEDIHUB SCIENCETEC PRIVATE LIMITED, ROOM NO:2, GROUND FLOOR, FG STORE, P NO:4, NH7, INDUSTRIAL AREA - II (CMDA), TAMILNADU, MARAIMALAI NAGAR - 603 209. PERIOD FROM 20.04.2022 TO 19.04.2027

**Payment Mode** Offline **Payment Type** Cash **Payment Status** Pending

**Challan Amount (Rs.)** 3000 **Bank Name** SBI

**Amount (in words)** Three Thousand Rupees only. **Bank ref no.** CPABOJIRQ3

**Remitter Signature**

**For Bank Use**

**Bank Branch Stamp and Signature of Cashier**



**Manager/Accountant**

Please Note\*, Department Transaction ID and Office Name fields are created only for 4 interface department Registration and Transport and GT for there specific requirements and the values entered in this fields are values passed by them not from IFHRMS.





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## 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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Non-Convention - 300Rs/-

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, Protective Cap (1/4 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.

Shelf life: 3 years

Sterile or Non sterile: Sterilized

Brand Name (if registered under the Trade Marks Act, 1999): SPICTRA

Place:

Date 30-Sep-21

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

State Licensing Authority



## 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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P V  
VIJAYALAKS  
HMI

Digitally signed by P V VIJAYALAKSHMI  
DN: c=IN, o=DIRECTORATE OF DRUGS CONTROL  
ADMINISTRATION, ou=DIRECTORATE OF DRUGS  
CONTROL,  
pseudonym=b93505c2236ca3e8a0e0ef4d80de0beb,  
2.5.4.20=4E6A3A28375A6249711332FF0C1322A6674  
3BBB919268106A9801954904FB22,  
postalCode=600006, st=Tamil Nadu,  
serialNumber=eb6c1d22ace66ff80291829ecfaf34b53  
90656ea630f8d9cc791723342f159d1, cn=P V  
VIJAYALAKSHMI  
Date: 2022.12.29 13:18:43 +05'30'

1	<p>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</p> <p>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).</p> <p>Class of medical device:Class B</p> <p>Material of construction:1.Heat Exchanger Shell &amp; integrated connectors- Poly carbonate Poly Carbonate Clear -Resin Code : Lexan 144R,164R / Equivalent; 2.Top &amp; 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</p> <p>Dimension(if any):40ml -Priming capacity.</p> <p>Shelflife:36 months / 3 Years</p> <p>Sterile or Non sterile:Both</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):SPICTRA</p>
2	<p>Generic Name:Cardiopulmonary bypass cardiectomy suction line blood filter (Cardiectomy Reservoir) ISO 15674  Model No.:M7C / 06/2020 / CARDIOTOMY RESERVOIR ADULT - Capacity - 2 Liters ,M4C / 06/2020 / CARDIOTOMY RESERVOIR - Capacity -3 Liters</p> <p>Intended Use:Cardiectomy 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 cardiectomy suction line during cardiopulmonary bypass surgery (6 Hours)</p> <p>Class of medical device:Class B</p> <p>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 &amp; 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.</p> <p>Dimension(if any):Volume - 2 / 3 liters capacity</p> <p>Shelflife:36 months / 3 Years</p> <p>Sterile or Non sterile:Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):SPICTRA</p>



3	<p>Generic Name: Vacuum-powered body fluid suction apparatus (Chest / Thoracic Drainage System)</p> <p>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</p> <p>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.</p> <p>Class of medical device: Class B</p> <p>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 &amp; Vacuum line – PVC soft Translucent, Hardness 50-55 SH.</p> <p>Dimension(if any): 2 liter capacity</p> <p>Shelflife: 36 months / 3 Years</p> <p>Sterile or Non sterile: Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999): SPICTRA</p>
4	<p>Generic Name: Closed wound drainage tube (Chest drain catheter) ISO 20697</p> <p>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</p> <p>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</p> <p>Class of medical device: Class B</p> <p>Material of construction: 1. Catheter tubes – Medical grade Polyvinyl chloride; 2. Multibarbar Connectors – Polypropylene; 3. Plug – Soft PVC</p> <p>Dimension(if any): Length - 45cm</p> <p>Shelflife: 36 months / 3 Years</p> <p>Sterile or Non sterile: Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999): SPICTRA</p>

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pseudonym=b93505c2236ca3e8a0eef4d80de0beb,  
2.5.4.20=4E6A3A28375A6249711332FF0C1322A66743BBB  
B919268106A9801954904FB22, postalCode=600006,  
st=Tamil Nadu,  
serialNumber=eb6c1d22ace66ff80291829ecfaf34b5390656  
ea630f8d9cc791723342f159d1, cn=P V VIJAYALAKSHMI  
Date: 2022.12.29 13:19:29 +05'30'



5	<p>Generic Name:Cardiopulmonary bypass vascular tubing (ISO 15676)</p> <p>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</p> <p>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.</p> <p>Class of medical device:Class B</p> <p>Material of construction:Tubing – Medical grade Poly vinyl chloride</p> <p>Dimension(if any):1/4 inch X 12 feet; 1/2 inch X 10 feet; &amp; 3/8 inch X 10 feet.</p> <p>Shelflife:36 months / 3 Years</p> <p>Sterile or Non sterile:Both</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):SPICTRA</p>
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P V  
VIJAYALAKSHMI

Digitally signed by P V VIJAYALAKSHMI  
DN: c=IN, o=DIRECTORATE OF DRUGS CONTROL  
ADMINISTRATION, ou=DIRECTORATE OF DRUGS CONTROL,  
pseudonym=b93505c2236ca3e8a0e0ef4d80de0beb,  
2.5.4.20=4E6A3A28375A6249711332FF0C1322A66743BBB91  
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Nadu,  
serialNumber=eb6c1d22ace66ff80291829ecfaf34b5390656ea  
630f8d9cc791723342f159d1, cn=P V VIJAYALAKSHMI  
Date: 2022.12.29 13:19:46 +05'30'

Place:

Date28-Dec-22

State Licensing Authority





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## 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

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	<p>Generic Name:Perfusion Custom pack</p> <p>Model No.:NIL</p> <p>Intended Use:It is used to interconnect the patient and the products – Custom Perfusion pack – tubing set.</p> <p>Class of medical device:Class C</p> <p>Material of construction:Polyvinyl chloride tubings; Polycarbonate connctors;</p> <p>Dimension(if any):Tray diameter - 41.5cm ; Height - 13 to 16 cm</p> <p>Shelflife:3</p> <p>Sterile or Non sterile:Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):SPICTRA</p>

Place:

Date 26-Dec-22

VENUGOPAL G SOMANI

Digitally signed by VENUGOPAL G SOMANI  
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL  
ORGANIZATION, ou=DRUGS CONTROLLER GENERAL (INDIA),  
pseudonym=112046a34e21727bacb255748732c456d249073e  
55e953d9cb5b58748ee3113c, postalCode=110002, st=DELHI,  
serialNumber=e977241aa0c0bba41522525ffca0705074b4997e6  
b7d4b5e9b1e7282a0a5d, cn=VENUGOPAL G SOMANI  
Central Licensing Authority



Directorate General of Health Services  
Central Drugs Standard Control Organisation  
Ministry of Health and Family Welfare  
(Medical Device and Diagnostic Division)

File No : MD/PostAppr/2022/13797

FDA Bhawan, Kotla Road  
New Delhi-110002  
Phone No-011-23236965  
Fax: 23236973  
Date: 23-Feb-2023

To

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 Email: qas@spictra.com

Sub: Post approval change in Manufacturing License No. MFG/MD/2022/000710 Dated 26/12/2022 .

Sir,

This is with reference to your application number MD/PostAppr/2022/13797 dated 23/02/2023 regarding the above subject.

The Change in Manufacturing Licence No. MFG/MD/2022/000710 as mentioned below is approved with subject to the same condition of licence.

Change Description	Product Name(Brand Name)	In Place of	To be Read as
Amendment/Correction/Others	Perfusion Custom pack (SPICTRA)	Details as per existing approved licence.	Pump head lines, Re-circulation lines, AV Loop Lines, Cardiotomy Suction Lines, Cardioplegia lines, Gas Lines, Connector Straight, Y and Luer Lock, Purge Line with/without Stop cock or non return valve, Stop Cock/Extension Lines, Arterial Bubble Trap, Arterial Filter, Gas Line Filter

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PULIJALA

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PRASAD PULIJALA  
DN: c=IN, o=CENTRAL DRUGS STANDARD  
CONTROL ORGANIZATION, ou=DRUGS  
CONTROLLER GENERAL D,  
2.5.4.22=741c78257ec25  
f7644d068633dabd1e7854fe5b0c57a5dd7,  
postalCode=110002, st=delhi,  
serialNumber=BF1721DC390050E6F28864E2  
A2EDAC55743FE97981D2D4ABFDEDE60EF6  
49C865, cn=BALAJI NARSINGA PRASAD  
PULIJALA  
Date: 2023.02.23 11:39:51 +05'30'





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## 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	<p>Generic Name:Hemoconcentrator set (Haemoconcentrator)</p> <p>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</p> <p>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.</p> <p>Class of medical device:Class C</p> <p>Material of construction:Filter - Polyethersulfone; Housing - Polycarbonate; blood and drain lines - Polyvinyl chloride; Potting material - Polyurethane.</p> <p>Dimension(if any):Diameter - 6.5cm ; Length - for 0.3 sq.m - 12cm; for 0.7sq.m - 21cm</p> <p>Shelflife:36 months / 3 Years</p> <p>Sterile or Non sterile:Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):SPICTRA</p>

Place:

Date 01-Jun-23

RAJEEV SINGH  
RAGHUVANSHI

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email=rajeev.singh@cdsco.gov.in, serial=657F5E47D940985D8F03BDC902D0E1F  
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## 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	<p><b>Generic Name:</b> Arterial Line Blood Filter</p> <p><b>Model No.:</b> M5AF / 06/2020 - Arterial Blood filter with loop - Adult with loop, M6AF / 06/2020 - Arterial Blood filter without loop - Adult without loop</p> <p><b>Intended Use:</b> Arterial line Blood filter (ABF) is used for removal of air micro aggregates, surgical debris &amp; particles, without any damage to the blood components. This is a single-use device</p> <p><b>Class of medical device:</b> Class C</p> <p><b>Material of construction:</b> Filter - Polyester; Filter frame - Polypropylene; Base holder- ABS; Housing - Polycarbonate;</p> <p><b>Dimension(if any):</b> Diameter - 6.5cm ; Length - 18cm;</p> <p><b>Shelflife:</b> 36 months / 3 Years</p> <p><b>Sterile or Non sterile:</b> Sterilized</p> <p><b>Brand Name(if registered under the Trade Marks Act, 1999):</b> SPICTRA</p>
2	<p><b>Generic Name:</b> Cardio pulmonary bypass defoamer</p> <p><b>Model No.:</b> 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</p> <p><b>Intended Use:</b> 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</p> <p><b>Class of medical device:</b> Class C</p> <p><b>Material of construction:</b> Filter - Polyester; Filter frame - Polypropylene; Base holder- ABS; Housing - Polycarbonate;</p> <p><b>Dimension(if any):</b> Capacity - 200ml/120ml/25ml</p> <p><b>Shelflife:</b> 36 months / 3 Years</p> <p><b>Sterile or Non sterile:</b> Sterilized</p> <p><b>Brand Name(if registered under the Trade Marks Act, 1999):</b> SPICTRA</p>

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2.5.4.20=420776901C0981003205A9750023F0D1  
1b680a91f08773480400a43ee361b,  
postalCode=110002, st=Delhi,  
serialNumber=6575e47d940985d8f03bdc902d0e1f  
e73cfa12a1a126ea94fa5701124a19013, cn=RAJEEV SINGH RAGHUVANSHI  
Date: 2024.07.09 10:22:24 +05'30'

Place:

Date 08-Jul-24

Central Licensing Authority

