



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

BALAJI
NARSINGA
PRASAD
PULIJALA

Digitally signed by BALAJI NARSINGA PRASAD PULIJALA
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ou=DRUGS CONTROLLER GENERAL D,
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postalCode=110002, st=delhi,
serialNumber=BF1721DC390050E6F28864E2
A2EDAC55743FE97981D2D4ABFDEDE60EF6
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Date: 2023.02.23 11:39:51 +05'30'