



BSCIC

Certificate

MEDICAL DEVICE -
QUALITY MANAGEMENT SYSTEM

This is to certify that:

J.MITRA & BROS.

**E-30, INDUSTRIAL AREA,
SONIPAT – 131001, HARYANA, INDIA**

Hereby granted the Certificate Number: **BN24309/22919**

Rev. 01

Subsequent to the **Audit** of the organization, it has been found to be operating a Medical Device-Quality Management System which complies with the requirements of

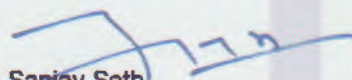
ISO 13485:2016

For the following scope:

Design Manufacture and Supply of Custom Perfusion System, Cardiopulmonary Bypass Arterial Line Blood Filter, Hemoconcentrator Set, 3-Way Stopcock as an Accessory to Perfusion Sets, Y-Connector as an Accessory to Perfusion Sets, Arterial Cannula, Venous Cannula, Coronary Artery Cannula, Vena Cava Cannula, Ventricular Cannula, Heart Lungs Bypass Unit Tube, Cardiopulmonary Bypass Heat Exchanger, M.T.P. Cannula, IV Infusion Set, Blood Transfusion Set, Exchange, Yankauer Suction Set, Nebulizer Mask, Hemodialysis Catheter Kit, Introducer Needle, Spinal Needles, Gas Line Filter, 3 Way Stop Cock With Extension Line, Lung Exerciser, Heat and Moisture Exchange/Filter, Bain Circuit, Pressure Monitoring Line, Suckers, Ventilator Circuit, Twin Bore Nasal Oxygen Set, Catheter Mount, Hollow-Fibre Haemodialysis Dialyser, Chest Drainage Bottle, Soda Lime, Carbon Dioxide Absorber

Technical Area: General Non-Active, Non-Implantable Medical Devices, Non-Active Devices for Anesthesia, Emergency and Intensive Care, A.1.1.1, Non-Active Devices for Injection, Infusion, Transfusion and Dialysis, A.1.1.2, Respiratory Devices, Devices including Hyperbaric Chambers for Oxygen Therapy, Inhalation Anaesthesia A.1.2.2, General Active Medical Devices, Active Surgical Devices, A.1.2.4

For
BSCIC CERTIFICATIONS PVT.LTD.


Sanjay Seth
Managing Director

Originally Registered:	25-Jul-2025	1st Surveillance Due on:	24-Jul-2026
Issue Date:	24-Dec-2025	2nd Surveillance Due on:	24-Jul-2027
Expiry Date:	24-Jul-2028		

(In case if Surveillance Audit is not allowed to be conducted; this Certificate shall be Suspended/Withdrawn).

Please Re-validate this certificate's status at www.bscic-icc.com at REGISTRATION STATUS.

This Certificate of Registration is granted subject to relevant provisions of the BSCIC Certifications PVT. LTD. Contract Terms & Scheme for Registration Form B018 (Latest Version). Please see B018 at our website www.bscic-icc.com.

The certificate of Registration remains the property of BSCIC Certifications Pvt. Ltd. and shall be returned immediately upon request. BSCIC Headquarters: 8work, 1st Floor, 5B/15A, Crown Plaza Mall, Faridabad - 121 007, Haryana, India.

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Registered

