

## **BSCIC**

## Certificate

MEDICAL DEVICE-QUALITY MANAGEMENT SYSTEM

This is to certify that:

## ATLANTIC BIO MEDICAL PVT. LTD.

H.O.: 101, BUSINESS POINT 349, WESTERN EXPRESS HIGHWAY ANDHERI EAST - 400 069, MAHARASHTRA, INDIA UNIT: 43/2B&3B, 44/3B&4B, SAWARSAI VILLAGE, TAL. PEN, DIST. RAIGAD – 402 107 MUMBAI, MAHARASHTRA, INDIA

Hereby granted the Certificate Number:

BN20967/20433

Subsequent to the Assessment 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:

Manufacturing and Supplying of Conc. Haemodialysis Solution B.P. Part I & II, Dry Citracon Haemodialysis Conc. Part I & II, Renabag Haemodialysis Bicarbonate Bag, Renacart Haemodialysis Bicarbonate Cartridge, Rena-multicart Haemodialysis Bicarbonate cartridge, Renaclean Cold Sterilant, Renasteril Hot Disinfectant, Renaclean Surface Disinfectant

Technical Area: General Non-Active, Non-Implantable Medical Devices, Non-Active Devices for Injection, Infusion, Transfusion and Dialysis, A.1.1.2, Non-Active Medical Devices for Disinfecting, Cleaning, Rinsing, A.1.1.8

For

BSCIC CERTIFICATIONS PVT.LTD.

Originally

21-Sep-2022 1st Surveillance Due on: 20-Sep-2023

Registered:

Issue Date: 21-Sep-2022

2nd Surveillance Due on: 20-Sep-2024

Expiry Date: 20-Sep-2025

Sanjay Seth Managing Director

(In case if Surveillance Audit is not allowed to be conducted; this Certificate shall be Suspended/Withdrawn).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.bsc-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 8018 (Latest Version). Please see 8018 at our website www.bsc-icc.com.

Registration Form B018 (Latest Version). Please see B018 at our website www.bsc-icc.com.
The certificate of Registration remains the property of BSCIC Certifications Pvt. Ltd. and shall be returned immediately upon request.
BSCIC Headquarters: &work, 1st Floor, 5B/15A, Crown Plaza Mall, Faridabad - 121 007, Haryana, India.

Version No. 1







