

BSCIC

Certificate

MEDICAL DEVICE-QUALITY MANAGEMENT SYSTEM

This is to certify that:

STERILE SAFEOUIP AND CHEMICALS LLP

31, PANCHRATNA INDUSTRIAL ESTATE, INSIDE PIRANA GATE. S.P. RING ROAD, VILLAGE PALDI-KANKAJ, DASKROI AHMEDABAD - 382 425, GUJARAT, INDIA

Hereby granted the Certificate Number:

BN22143/21091

Rev. 00

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:

Design, Development, Manufacturing, Installation and Servicing of Erythrocyte Sedimentation Rate (ESR) Analyzer and Biochemistry (Clinical Chemistry) Analyzer

Technical Area: Reagents and Reagent Products, Calibrators and Control Materials for: Immunochemistry (Immunology), A.1.4.2, Haematology/ Haemostasis/ Immunohematology, A.1.4.3

For

BSCIC CERTIFICATIONS PVT.LTD.

Originally

12-Jun-2023

1st Surveillance Due on: 11-Jun-2024

Registered: Issue Date:

12-Jun-2023

2nd Surveillance Due on: 11-Jun-2025

Expiry Date:

11-Jun-2026

BSCIC Headquarters: &work, 1st Floor, 5B/15A, Crown Plaza Mall, Faridabad - 121 007, Haryana, India.

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(In case if Surveillance Audit is not allowed to be conducted; this Certificate shall be Suspended/Withdrawn).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

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