



BSCIC

Certificate

MEDICAL DEVICE -
QUALITY MANAGEMENT SYSTEM

This is to certify that:

BIOGENIX INC. PRIVATE LIMITED

**SITE 1: B-19/A, S.I.L ANCILLARY ESTATE, AMAUSI INDUSTRIAL AREA
NADARGANJ, LUCKNOW - 226008, UTTAR PRADESH, INDIA**

**SITE 2: B-24, S.I.L ANCILLARY ESTATE, AMAUSI INDUSTRIAL AREA
NADARGANJ, LUCKNOW - 226008, UTTAR PRADESH, INDIA**

Hereby granted the Certificate Number:

BN24433/23160

Rev. 00

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:

Site1: Design & Development, Manufacture, Sale and Dispatch Activities Related to Biochemistry, Immunology (Rapid Cards, ELISA, CLIA and Serology) Pathological Kits, Veterinary Products, Microbiology, Blood Culture Bottles, Reagents, Instruments and Trading of Consumables.

Site 2: Design & Development, Manufacture, Sale and Dispatch Activities Related to Immunology (Rapid Cards), Pathological Kits, Reagents and Trading of Consumables.

Technical area: Reagents and Reagent Products, Calibrators and Control Materials for: Clinical Chemistry, A.1.4.1, Immunochemistry (Immunology), A.1.4.2, Haematology/ Haemostasis/ Immuno-haematology, A.1.4.3, Microbiology, 1.4.4

For
BSCIC CERTIFICATIONS PVT. LTD.

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


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(In case if Surveillance Audit is not allowed to be conducted; this Certificate shall be Suspended/Withdrawn).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.
BSCIC Headquarters: &work, 1st Floor, 5B/15A, Crown Plaza Mall, Faridabad - 121 007, Haryana, India.

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Registered



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