



BSCIC

Certificate

M E D I C A L D E V I C E -
Q U A L I T Y M A N A G E M E N T S Y S T E M

This is to certify that:

BIOGENY DIAGNOSTICS PVT. LTD.

PLOT NO. 1-2, SURVEY NO. 169 (SISODRA), NEAR PLOT NO. 425,
NEW G.I.D.C, KABILPORE, NAVSARI - 396 424,
GUJARAT, INDIA

Hereby granted the Certificate Number:

BN19610/18754

Rev. 03

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, Manufacturing and Supply of Diagnostics Reagents, Instruments and Reagent Products, Calibrators and Control Material for Clinical Chemistry, Immunology, Hematology, Microbiology, Marketing and Servicing of IVD Equipment (Technology – Hematology & Clinical Chemistry) and Trading of IVD Equipment (Technology – CLIA & POCT)

Technical area: Reagent and Reagent products, Calibrators and Control Material for: Clinical Chemistry, A.1.4.1, Immunochemistry (Immunology), A.1.4.2, Hematology /Haemostasis/Immunohematology, A.1.4.3, Microbiology, A.1.4.4, Infectious Immunology, A.1.4.5, In Vitro Diagnostic Instruments and Software, A.1.4.8

For
BSCIC CERTIFICATIONS PVT.LTD.

Originally Registered: 01-Jun-2020 1st Surveillance Due on: 30-May-2024
Issue Date: 19-May-2023 2nd Surveillance Due on: 30-May-2025
Expiry Date: 31-May-2026


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(In case if Surveillance Audit is not allowed to be conducted; this Certificate shall be Suspended/Withdrawn).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: 8work, 1st Floor, 5B/15A, Crown Plaza Mall, Faridabad - 121 007, Haryana, India.

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Registered

