

Certificate of Registration

This is to Certify that
Medical Device Quality Management System of

M/s. BIOGENIX INC. PVT. LTD.

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

has been assessed and found to conform to the requirements of
ISO 13485:2016
for the following scope :

DESIGN & DEVELOPMENT, MANUFACTURE, SALES AND POST DELIVERY
ACTIVITIES RELATED TO BIOCHEMISTRY, IMMUNOLOGY (RAPID CARDS
AND ELISA), SEROLOGY KITS AND REAGENTS, INSTRUMENTS.

Certificate No	: 24EMNS41	Issuance Date	: 09/09/2024
Initial Registration Date	: 09/09/2024		
Date of Expiry*	: 08/09/2027		
1st Surv. Due	: 09/08/2025	2nd Surv. Due	: 09/08/2026

Director



(Scan to Verify)

Assurance Quality Certification LLC

Head Office: Sharjah Media City, SHAMS, Sharjah, UAE. e-mail: info@aqcworld.com
Key Location: A-60, Sector - 2, Noida, Uttar Pradesh, 201301, India.

*Validity of the Certificate is subject to successful completion of surveillance audit on or before of due date. (In case surveillance audit is not allowed to be conducted, this certificate shall be suspended/withdrawn).

Certificate Verification: Please Re-check the validity of certificate at <http://www.aqcworld.com/activeclients.aspx> or www.aqcworld.com at Active Clients.
Certificate is the property of Assurance Quality Certification LLC and shall be returned immediately when demanded

Certificate of Registration



This is to Certify That The Quality Management System of

M/S BIOGENIX INC. PRIVATE LIMITED

OFFICE ADDRESS: K-796, KANPUR ROAD, AASHIANA COLONY,
LUCKNOW - 226012, UTTAR PRADESH, INDIA.

FACTORY ADDRESS: B-19/A, S.I.L ANCILLARY ESTATE, AMAUSI
INDUSTRIAL AREA, NADARGANJ, LUCKNOW - 226008 (U.P), INDIA.

has been assessed and found to conform to the requirements of

ISO 9001:2015

for the following scope :

MANUFACTURER & SUPPLIER OF DIAGNOSTICS KITS/REAGENTS
(BIOCHEMISTRY, IMMUNOLOGY, RAPID CARDS, ELISA, SEROLOGY, CLIA &
VETERINARY), MICROBIOLOGY KITS/REAGENTS, MOLECULAR AND LIFE
SCIENCE KITS/REAGENTS, PLASTICWARES & LABORATORY
EQUIPMENTS/INSTRUMENTS.

Certificate No	24DQMI75		
Initial Registration Date	: 08/04/2024	Issuance Date	: 08/04/2024
Date of Expiry*	: 07/04/2027		
1st Surve. Due	: 08/03/2025	2nd Surve. Due	: 08/03/2026

DIRECTOR

ROHS Certification Pvt. Ltd.

A-60, 3rd Floor (T1), Sector 02, Noida, Gautam Buddha Nagar, Uttar Pradesh-201301

e-mail : info@rohscertification.co.in | website : www.rohscertification.co.in

The Registration is not a Product Quality Certificate. *Subject to successful completion of surveillance audits, Visit for verification on www.rohscertification.co.in
Certificate is the property of ROHS and return when demanded



Certificate of Compliance



We hereby declare that the technical files of all the items in each product group of complied with the requirements of the (98/79/EC) In-Vitro Diagnostic Devices Directive.

Certificate No.: CE-5558

Manufacturer

Name : **BIOGENIX INC. PRIVATE LIMITED**

Address : **OFFICE ADDRESS: K-796, KANPUR ROAD, AASHIANA COLONY,
LUCKNOW-226012, UTTAR PRADESH, INDIA.
FACTORY ADDRESS: B-19/A, S.I.L ANCILLARY ESTATE,
AMAUSI INDUSTRIAL AREA, NADARGANJ, LUCKNOW-226008
(U.P.) INDIA**

Products : **DIAGNOSTICS KITS/REAGENTS (BIOCHEMISTRY, IMMUNOLOGY,
RAPID CARDS, ELISA, SEROLOGY, CLIA & VETERINARY), MICROBIOLOGY
KITS/REAGENTS, MOLECULAR AND LIFE SCIENCE KITS/REAGENTS,
PLASTICWARES & LABORATORY EQUIPMENTS/INSTRUMENTS.**

Complies with the requirements applicable to it

The quality system file has been assessed, approved and is subject to continuous surveillance according to the (98/79/EC) In-Vitro Diagnostic Devices Directive.

This certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type-examination procedures, if requested.
2. The certificate remains valid until the manufacturing conditions or the quality systems are changed.
3. The certificate validity is conditioned by positive results or surveillance audits.
4. After fulfilling the relevant EU legislation, the manufacturer shall affix to each device, of the referenced models.
5. The CE mark as shown above can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of conformity and compliance with all relevant EC Directives. The statement is based on a single evaluation of one sample of above mentioned product. It does not imply an assessment of the whole production.

Validity of this certificate can be verified at www.ukcertifications.org.uk/verify

Date of Certification	16 th March 2024
1 st Surveillance Audit Due	15 th March 2025
2 nd Surveillance Audit Due	15 th March 2026
Certificate Expiry (subject to the company maintaining its system to the required standard)	15 th March 2027



Authorised Signatory

