

CERTIFICATE



No. 5Q250117.B0Q08

Certificate's Holder: BIOGENIX INC. PVT LTD
B-19/A, S.I.L Ancillary Estate, Amausi Industrial Area, Nadarganj, Lucknow -226008

Certification ECM Mark



Product: HISTOPATHOLOGY AND BIOCHEMISTRY INSTRUMENTS
Model(s): *(see the following annex)*

Verification to: Standard:
IEC 60601-1:2005+AMD1:2012+AMD2:2020 CSV,
IEC 60601-1-2:2014+AMD1:2020 CSV, IEC 61326-1:2020,
EN 60529:2018, EN 61000-3-2:2014, EN 61000-3-3:2013,
EN 61000-4-4:2012, IEC 61300-3-35:2022,
IEC 61010-1:2010+AMD1:2016 (Reference 98/79/EC- IVD),
CSV, IEC 61010-2-081:2019 RLV,
IEC 61010-2-101:2018 RLV (Reference 98/79/EC-IVD),
UL 61010-1 (Reference 98/79/EC- IVD)
related to CE Directive(s):
2014/35/EU (Low Voltage)
2014/30/EU (Electromagnetic Compatibility)

Remark:

The manufacturer has voluntarily decided to submit its documents concerning the above-mentioned product for verification. Ente Certificazione Macchine confirms that the documentation made available and immediately returned to it, as containing sensitive data, meets the essential requirements of the above-mentioned directive/standard. The verification activity carried out exclusively concerned the technical documentation and no verification was carried out on the product. This document cannot replace the EC Declaration of Conformity. This document was issued in accordance with regulation RGVOL01 published on the website of www.entecerma.it and concerning voluntary certifications with a non-notified procedure.

Issuance date: 17 January 2025

Expiry date: 16 January 2030

For online check:



Approver
Ente Certificazione Macchine
Legal Representative
Luca Bedonni





Annex I

No. 5Q250117.B0Q08

Model(s):

1. Automated Blood Culture Instrument - 24/32/48/64/96/128/256 Model
BugZ 24, BugZ 32, BugZ 48, BugZ 64, BugZ 96, BugZ 128, BugZ 256
2. Haematology Analyzer - 3/5 part/5part + autoloader model
Trinity 3, Trinity 5, BI-3100
3. Biochemistry analyzer - Semi Automatic
BI-251, BI-501, BI-501 PLUS, BI-10S
4. Biochemistry analyser - Fully Automatic - 200/480/600/800 test/hr models
BI-200, BI-380, BI-480, BI-600, BI-800
5. Elisa Reader & Washer
Cypher
6. Fully Automated TRFIA Instrument
Neo 2, Neo 6, Neo 8, Neo 12
7. Urine Analyzer
BI-400
8. Point of Care analyzer
BI-180
9. HPLC Analyzer
Hulk
10. Chemiluminescence Analyzer - 100/200/400 tests throughput per hour
Morpheus, BI-CLIA100, BI-CLIA200, BI-CLIA400, BI-2000
11. Digital PCR
BI-DPCR4, BI-DPCR16, BI-DPCR32
12. PCR Instrument 48/96 well
BI-PCR48, BI-PCR96
13. Coagulation analyzer
BI-100CL, BI-200CL, BI-400CL
14. ABG Analyzer
Loki
15. Fluorescence analyzer for Autoimmune & Allergen testing
BI-MFA24, BI-MFA48