## Certificate of Compliance



PRODUCT CERTIFICATE
EC Attestation of Conformity

## TRANSASIA BIO -MEDICALS LTD.

Address: Transasia House, 8 Chandivali Studio Road,

Andheri (E), Mumbai – 400072, India

Is in compliance with Directive

IVD - 98/79/EC LVD - 2006/95/EC EMC - 2004/108/EC

## For The following product

- 1. AUTOMATED CLINICAL CHEMISTRY ANALYZERS
- 2. SEMI AUTOMATED CLINICAL CHEMISTRY ANALYZERS
- 3. SEMI AUTOMATED MICRO PLATE READER/WASHER FOR IMMUNOLOGY AND MICROBIOLOGY
- 4. AUTOMATED IMMUNOASSAY ANALYZERS
- 5. AUTOMATED HPLC ANALYZERS
- 6. AUTOMATED ESR DETERMINATION ANALYZERS

(Product details as per Supplement 001)

In accordance with TCF No. CE/01

The present certificate exclusively refers to the product above identified, in accordance to TCF submitted in PICL. Any Changes or modification implemented on the mentioned Product will not be covered by this certificate.

Registration No.: PICL/CE/0824/0041 Certificate Issue Date: 03.08.2024 1st Surveillance: 08.2025

Certificate Renewal Date: 02.08.2027 2nd Surveillance: 08.2026



**Head of Certificate** 





This Certificate of Registration is granted subject to the Regulations approved by the Board.

PROGRESSIVE INTERNATIONAL CERTIFICATIONS LTD.
Office 4 219 Kensington High Street Kensington London W8 6RD England

Office 4, 219, Kensington High Street, Kensington, London, W8 6BD, England. E-mail.: info@picluk.com, Website: www.picluk.com

For current validity of this certificate. Please visit our website

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SUPPLEMENT 001 ATTACHMENT FOR CERTIFICATE NO. PICL/CE/0824/0041 SUPPLEMENT 001 DATED 03/08/2024 PRODUCT SERVICE FOR THE PRODUCT(S) / PRODUCT CATEGORY (IES):

- 1. Automated Clinical Chemistry Analyzers
  - a) EM 100 / XL-100

  - b) EM Destiny 180 / XL-180 c) EM 200 / XL-200 / XL-400 d) EM 360 / XL-300 / XL-600

  - e) XL-640
  - f) XL-1000
- 2. Semi-automated Clinical Chemistry Analyzers
  - a) Chem 5 plus V2
  - b) Chem 5X / Chem 5V3
  - c) Chem-7
  - d) Chem Touch
  - e) Chem 6
- 3. Semi-automated Micro Plate Reader / Washer for Immunology and Microbiology
  - a) LisaScan EM
  - b) LisaWash
  - c) LisaWash II
- **Automated Immunoassay Analyzers** 
  - a) Elan 30s
  - b) Lisa XL
  - c) Lisa M
  - d) IA-40
- 5. Automated HPLC Analyzers
  - a) Hb-Vario
  - b) Hb 820
- **Automated ESR Determination Analyzers** 
  - a) ESL 30
  - b) ESL 10

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