

Certificate of Conformity

CE

Confirms that the Class 1 complies according to the directive Council Directive on Medical Devices 93/42/EEC as Amended 2007/47/EC & directives GPSD - 2001/95/EC General Safety Directive

Certificate No.: CE-8068

Manufacturer

Name : KEE DIAGNOSTICS PVT. LTD.

**Address : A-8, 3RD FLOOR NARAINA INDUSTRIAL AREA,
PHASE II NEW DELHI -110028 INDIA**

Product : As Per Appendix Page 4

Complies with the requirements applicable to it

The manufacturer's technical documentation as required for Medical Council according to the directive 93/42/EEC has been reviewed and found to comply with the requirements for Class I Council Directive on Medical Devices 93/42/EEC as Amended 2007/47/EC. & directives GPSD - 2001/95/EC General Safety Directive Any significant changes in the design or construction of the product, not agreed upon by us, this declaration will lose its validity

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.

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 25th July 2026

1st Surveillance Audit Due 24th July 2027

2nd surveillance Audit Due 24th July 2028

Certificate Expiry (subject to the company maintaining its system to the required standard) 24th July 2029



Authorised Signatory



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Certificate of Conformity

Appendix-I

Appendix to Certificate no.:- **CE-8068**

Manufacturer :-

KEE DIAGNOSTICS PVT. LTD.

Address :

**A-8, 3RD FLOOR NARAINA INDUSTRIAL
AREA, PHASE II NEW DELHI - 110028 INDIA**



This certificate referred to above covers the following products like:

Products Group:

- Acid Phosphatase
- ADA
- Albumin
- Alkaline Phosphatase (ALP)
- Alkaline Phosphatase (ALP) Lypho
- Alpha HBDH
- ALT(SGPT)
- ALT(SGPT) Lypho
- Ammonia
- Amylase
- Angiotensin Converting Enzyme (ACE)
- Anti CCP
- Apolipoprotein A1 (APO-A1)
- Apolipoprotein B (APO-B)
- AST(SGOT)
- AST(SGOT) Lypho
- Bicarbonate
- Bilirubin (T&D)
- Bilirubin Direct
- Bilirubin Direct (DCA)
- Bilirubin Total
- Bilirubin Total (DCA)
- Calcium ARS
- Calcium OCPC
- Chloride
- Cholesterol
- Cholesterol Lypho
- Cholinesterase
- CK-MB
- CK-MB Lypho
- CK-Nac
- CK-Nac Lypho

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Certificate of Conformity

Appendix-II

Appendix to Certificate no.:- **CE-8068**

Manufacturer :-

KEE DIAGNOSTICS PVT. LTD.

Address :

**A-8, 3RD FLOOR NARAINA INDUSTRIAL
AREA, PHASE II NEW DELHI - 110028 INDIA**



This certificate referred to above covers the following products like:

Products Group:

- Copper
- Creatinine
- Creatinine SLR
- Creatinine Enzymatic
- Cystatin C
- D Dimer
- Ferritin
- Fructosamine
- G6PDH
- Gamma - GT
- Glucose
- Glucose Lypho
- Glucose Hexokinase
- Glycated Serum Protein Assay
- Haemoglobin - CMG
- HBA1C
- HDL Cholesterol (Direct)
- HDL-Cholesterol PPT
- Homocystein
- Immunoglobulin-A (IgA)
- Immunoglobulin-E (IgE)
- Immunoglobulin-G (IgG)
- Immunoglobulin-M (IgM)
- IRON
- UIBC
- TIBC
- Lactate
- LDH
- LDL Cholesterol
- Lipase
- Lipoprotein (a)
- Magnesium
- Micro Albumin



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This certificate is the property of UK Certification & Inspection Limited and shall be returned immediately on request.

71-75 Shelton Street, Covent Garden, London, WC2H 9JQ, United Kingdom

Website:- www.ukcertifications.org.uk, email:- info@ukcertifications.org.uk

Company No. 11847851



Certificate of Conformity

Appendix-III

Appendix to Certificate no.:- **CE-8068**

Manufacturer :-

KEE DIAGNOSTICS PVT. LTD.

Address :

**A-8, 3RD FLOOR NARAINA INDUSTRIAL
AREA, PHASE II NEW DELHI - 110028 INDIA**



This certificate referred to above covers the following products like:

Products Group:

- Micro Protein
- Phosphorus
- Potassium
- Procalcitonin (PCT)
- Pyruvate
- Sodium
- Total Bile Acid
- Total Protein
- Triglycerides
- Triglycerides Lypho
- Urea Berthelot
- Urea GLDH
- Urea GLDH Lypho
- Uric Acid
- Uric Acid Lypho
- Vitamin B12
- Vitamin D
- Zinc
- Urinalysis Reagent Strip
- Cleaner
- Detergent
- Detergent Cleaner
- Systemic Solution
- Multiclean Solution
- Rinse Solution Cvt
- Rinse Solution Prb
- Wash Solution
- X1 Cleaner Solution
- X2 Wash Solution
- VTM (Viral Transport Medium)
- Lipid Calibrator
- Multicalibrator
- Control Normal
- Control Abnormal
- Lipid Control 1



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Appendix-IV

Appendix to Certificate no.:- CE-8068

Manufacturer :-

KEE DIAGNOSTICS PVT. LTD.

Address :

A-8, 3RD FLOOR NARAINA INDUSTRIAL
AREA, PHASE II NEW DELHI - 110028 INDIA



This certificate referred to above covers the following products like:

Products Group:

- Lipid Control 2
- Diluent
- Lyse
- Rinse
- Electrolyte Reagent Pack
- Probe Wash
- ASO Latex
- CRP Latex
- RF Latex
- ASO Turbilatex
- CRP Turbilatex
- hsCRP Turbilatex
- RF Turbilatex
- Dengue IgG/IgM Antibody Card/Dipstick Test
- Dengue IgG Elisa
- Dengue IgM Elisa
- Dengue NS1 Antigen Card/Dipstick Test
- Dengue NS1 + IgG/IgM Combo Test
- Dengue NS1 Elisa
- Dengue IgG/IgM Elisa
- Malaria PF Antigen Card/Dipstick Test
- Malaria Pan/Antigen Card/Dipstick Test
- Malaria PF/Pan Antigen Card/Dipstick Test
- Malaria Pf/PV Antigen Card/Dipstick Test
- Malaria PF/PV Antibody Card/Dipstick Test
- T3 Elisa Kit
- T4 Elisa Kit
- TSH Elisa Kit
- T3(FT3) Elisa Kit
- T4(FT4) Elisa Kit
- Sickle Cell
- Widal
- ANA SMART Analyzer
- ANA LAB i 240
- ANA CELL 3100
- ANA CELL 5100
- ANALYTE - Electrolyte Analyzer
- ANALISA - Elisa Reader
- ANAWASH - Elisa Washer

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