



# Certificate of Compliance



We hereby declare that the technical files of all the items in each product group complies with the requirements of the Council Directive on **Medical Devices Regulations(EU) 2017/746-MDR**.

**Certificate No.: CE - 5239**

**Manufacturer : PARAMCARE LIFE SCIENCES PVT. LTD.**

**Address : G/F-12/13, EVERSHINE-2, SURVEY NO. 307/3/1, BALITHA  
N.H NO 48, VAPI, VALSAD, GUJARAT, 396191, INDIA**

**Products : AS PER ANNEXURE**

**Complies with the requirements applicable to it**

The quality system file has been assessed, approved and is subject to continuous surveillance according to the Council Directive on **Medical Devices Regulations(EU) 2017/746-MDR**.

**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 test report 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](http://www.ukcertifications.org.uk/verify)**

Date of Certification	5th January 2024
1 <sup>st</sup> Surveillance Audit Due	4th January 2025
2 <sup>nd</sup> Surveillance Audit Due	4th January 2026
Certificate Expiry	4th January 2027

**Authorised Signatory**



## Certificate of Compliance

## Appendix-II

Appendix to Certificate no.:- CE - 5239

Manufacturer: PARAMCARE LIFE SCIENCES PVT. LTD.



S. NO.	LIST OF PRODUCTS
	BIOCHEMISTRY TEST
1.	Alkaline Phosphatase Test Kit
2.	Adenosine Deaminase (ADA) Test Kit
3.	Ammonia Test Kit
4.	Albumin Test Kit
5.	Amylase Test Kit
6.	Bicarbonate Test Kit
7.	Bilirubin Total Test Kit
8.	Bilirubin Direct Test Kit
9.	Creatinine Enzymatic Test Kit
10.	Creatinine (Alkaline Picrate) Test Kit
11.	Chloride Test Kit
12.	CK-MB Test Kit
13.	CK-NAC Test Kit
14.	Copper Test Kit
15.	Calcium Test Kit
16.	CRP Turbilateral Test Kit
17.	Cholesterol Test Kit
18.	Glucose Test Kit
19.	Glucose Hexokinase Test Kit
20.	G6PD (quantitative) Test Kit
21.	G6PD (qualitative) Test Kit
22.	Homocysteine Test Kit
23.	Hemoglobin Test Kit
24.	HDL cholesterol Test Kit
25.	LDL cholesterol Test Kit
26.	Lipase Test Kit
27.	Lactate Dehydrogenase (LDH) Test Kit
28.	Magnesium Test Kit
29.	Phosphorus Test Kit
30.	Potassium Test Kit
31.	Sodium Test Kit
32.	SGPT Test Kit
33.	SGOT Test Kit
34.	Sickle Cell Assay Test Kit
35.	Total Protein Test Kit

*Daniel..*

Authorised Signatory



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

Website:- [www.ukcertifications.org.uk](http://www.ukcertifications.org.uk), email:- [info@ukcertifications.org.uk](mailto:info@ukcertifications.org.uk)

Company No. 11847851



Appendix to Certificate no.:- CE - 5239

Manufacturer: PARAMCARE LIFE SCIENCES PVT. LTD.



36.	Triglycerides Test Kit
37.	Urea (UV) Test Kit
38.	Uric Acid Test Kit
39.	Zinc Test Kit
<b>RAPID TEST KIT</b>	
40.	Chikungunya IgG/IgM Ab Rapid Test Kit
41.	Dengue IgG/IgM Ab Rapid Test Kit
42.	Dengue NS 1 Ag Rapid Test Kit
43.	Filariasis IgG/IgM Ab Rapid Test Kit
44.	hCG - Pregnancy Rapid Test Kit
45.	H.Pylori Ab Rapid Test Kit
46.	Influenza A+B Rapid Test Kit
47.	IgE Rapid Test Kit
48.	Japanese encephalitis IgM Ab Rapid Test Kit
49.	Leptospira IgG/IgM Ab Rapid Test Kit
50.	Luteinizing Hormone (LH) Rapid Test Kit
51.	Leishmania IgG/IgM Ab Rapid Test Kit
52.	Malaria Pf/Pv Ag Rapid Test Kit
53.	Rapid Drugs (Amphetamine) Rapid Test Kit
54.	Rapid Drugs (Barbiturates) Rapid Test Kit
55.	Rapid Drugs (Benzodiazepines) Rapid Test Kit
56.	Rapid Drugs (Cocaine) Screening Rapid Test Kit
57.	Rapid Drugs (Opiate (Morphine)) Rapid Test Kit
58.	Rapid Drugs (Cannabinoids) Rapid Test Kit
59.	Rapid Multi Drugs (6 in 1(Cocaine, Amphetamine, Barbiturate, Benzodiazepine, THC, Opiate) Rapid Test Kit
60.	Salmonella Typhi IgG/IgM Ab Rapid Test Kit
61.	Scrub Typhus IgG/IgM Ab Rapid Test Kit
62.	Sickle Cell Rapid Test Kit
63.	Sickle Cell Hb S, Hb A and Hb C Rapid Test Kit
64.	Salmonella Typhi and Paratyphi 'A' antigen Rapid Test Kit
65.	Syphilis Rapid Test Kit
66.	Troponin I Rapid Test Kit
67.	Troponin T Rapid Test Kit
<b>URINE STRIPS</b>	
68.	Urine Strips -2 Para (Glucose, Protein)
69.	Urine Strips -3 Para (Glucose, Protein, Ketone)
70.	Urine Strips -10 Para
71.	Urine Strips -12 Para

*Daniel..*

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