



Certificate No. : CE - 3237  
Rev. : 02.01

# Certificate

## OF COMPLIANCE

We hereby declare that the technical file of the product confirms with the requirement of **In Vitro Diagnostic Medical Devices Directive Regulated by 98/79/EC**

Manufacturer: **SELOI HEALTHCARE PVT. LTD.**

Address : **Unit 401 & 402, 4th Floor, Shri Sai Coperate Park, Laxmi Nagar, Off New Link Road, Goregaon west, Mumbai - 400 104, Maharashtra, India**

Products : **In Vitro Diagnostic Rapid Test Kit"as per Appendix-I - from Page 2 of 2**

The Certification body has performed an audit of the above product quality system covering design, manufacture and final inspection of the certified product. The Quality system has been assessed, approved and is subject to continuous surveillance according to the In Vitro Diagnostic Medical Devices Directive Regulated by 98/79/EC

**This Certificate is issued under the following Conditions:**

1. It applies only to the quality system maintenance 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 The Electromagnetic Compatibility are regulated by In In Vitro Diagnostic Medical Devices Directive Regulated by 98/79/EC 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.

Date of initial registration : Mar 18, 2021

Certificate expiry : Mar 07, 2024

Date of this certificate : Jul 06, 2023

Re-certification due : Mar 08, 2024

To check the status of the certificate, visit: <https://www.eac-council.org/validity.php>

(Authorized Signatory)



**European Certification Council**

101, Colbrand Grove Birmingham, B15 2BS, United Kingdom

[www.eac-council.org](http://www.eac-council.org)

[info@eac-council.org](mailto:info@eac-council.org)



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## Appendix : 1

Manufacturer: **SELOI HEALTHCARE PVT. LTD.**

Address : **Unit 401 & 402, 4th Floor, Shri Sai Coperate Park, Laxmi Nagar, Off New Link Road, Goregaon west, Mumbai - 400 104, Maharashtra, India**

S. No.	Products	S. No.	Products
01	HCG Pregnancy	18	C-reactive protein (CRP) Rapid Test
02	Dengue IgG/IgM	19	H. pylori Rapid Test
03	Typhoid IgG/IgM	20	JEV IgM Rapid Test
04	LH( Ovulation)	21	LEISHMANIA IgG/IgM Rapid Test
05	Covid -19 Ag	22	Procalcitonin (PCT) Rapid Test
06	Malaria Pf/Pv Ag	23	Sickle Cell Rapid Test Kit
07	Malaria Pf/Pan	24	TOXOPLASMA IgG/IgM RAPID TEST
08	Dengue Ns-1 Ag	25	Vitamin B12 Rapid Test
09	Dengue Combo(Ns-1+ IgG/IgM)	26	Urine Strips 2 Para (Glucose & Ketone)
10	Hiv ½ Triline	27	Urine Strips 2 Para (Glucose, Protein)
11	Syphilis Ab	28	Urine Strips 3 Para (Glucose, Protein & Ketone)
12	Hcv Ab	29	Ferritin Rapid Test
13	HBsAg	30	Leptospira IgM/IgG Rapid Test
14	Chikunguniya IgG/IgM	31	Scrub Typhus(TSUTSUGAMUSHI) IgM/IgG Rapid Test
15	Viral Transport Media(VTM)	32	Chikungunya IgG/IgM Rapid Test
16	CRP/MxA Antigen test	33	Immunoglobulin E(IgE) Rapid Test Kit
17	Vitamin D Rapid test	34	Filariasis IgG/IgM Rapid Test

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