



Certification & Inspection



# Certificate of Compliance



Confirms that the Class 1 complies according to the directive 93/42/EEC Medical Council Directive

**Certificate No.:** CE-1109

## Manufacturer

**Name** : ALPINE BIOMEDICALS PVT. LTD.

**Address** : Plot No- 348, Sector-2, Industrial Growth Center, HSIIDC, Saha, Ambala 133104 (Haryana), India

**Products** : In-Vitro Rapid Diagnostics Kits, Malaria Test Kit, Dengue Kit, Pregnancy Test Kit, Syphilis Test Kit, Chickengunea Test Kit, S.Typhi Rapid Test Kit

## 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 Medical Devices 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 not changed.
3. The certificate validity is conditioned by positive results of surveillance audits.
4. 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.co.uk/verify](http://www.ukcertifications.co.uk/verify)

Date of Certification	19 <sup>th</sup> February 2018
1 <sup>st</sup> Surveillance Audit Due	18 <sup>th</sup> February 2019
2 <sup>nd</sup> Surveillance Audit Due	18 <sup>th</sup> February 2020
Certificate Expiry (subject to the company maintaining its system to the required standard)	18 <sup>th</sup> February 2021

*Daniel..*

Authorised Signatory

