Certificate of Compliance

CE

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

Certificate No.: CE-2113

Manufacturer

Name **: Savi Rapid Diagnostics Company**

Address **: Plot No. 28, Saket Industrial Estate, Sarkhej – Bavla Highway, Moraiya, Dist – Ahmedabad, 382210, Gujarat, India**

Products

Name **: Diagnostics Kits and Reagents**

Models **: Urine Multi Parameter Strips, Rapid Card / Strip Test for Detection of Malaria PF / PV Antigen, Rapid Card / Strip Test for Detection of Malaria PF / PV Antibody, Rapid Card / Strip Test for Detection of Chikungunya IGM, Rapid Card / Strip Test for Detection of Dengue IGG / IGM Antibody, Rapid Card / Strip Test for Detection of Dengue IGG / IGM NS1 Antigen, Rapid Card / Strip Test for Detection of S. Typhi Salmonela Typhoid Antibody, Rapid Card / Strip Test for Detection of Leishmenia, Rapid Card / Strip Test for Detection of Syphilis Antibodies, Rapid Card / Strip Test for Detection of HCG (Pregnancy Test), Rapid Card / Strip Test for Detection of LH (Ovulution Test)**

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 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 above 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 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

Date of initial registration	26th March 2016
Date of this certificate	26th March 2016
Certificate expiry	25th March 2017
Recertification due (subject to the company maintaining its system to the required standard)	25th March 2019

Authorised Signatory