

Certificate of Compliance



We hereby declare that the technical file of product complied with the requirement of directives of the Council Directive on Medical Devices 93/42/EEC as Amended 2007/47/EC.

Certificate No.: CE-2448

Manufacturer

Name : MAPMYGENOME INDIA LIMITED

Address : PLOT NO. 12/2 SECTOR-I, ROYAL DEMEURE, HUDA TECHNO ENCLAVE, MADHAPUR, HYDERABAD - 500081, TELANGANA, INDIA

Products : SPOLIGO TB TM (SPOLIGOTYPING DIAGNOSTIC KIT)

Model : PCR BASED DETECTION OF MYCOBACTERIUM TUBERCULOSIS COMPLEX, GENERAL IVD

Complies with the requirements applicable to it

The quality system file has been assessed, approved and is subject to continuous surveillance according to the directives of the Council Directive on Medical Devices 93/42/EEC as Amended 2007/47/EC.

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.

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

19th April 2022

1st Surveillance Audit Due

18th April 2023

2nd Surveillance Audit Due

18th April 2024

Certificate Expiry (subject to the company maintaining its system to the required standard)

18th April 2025



Authorised Signatory



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