



CERTIFICATE

of Compliance

We hereby declare that the technical file of product complied with the requirement of directives
Class-I Medical Device Directive 93/42/EEC

Manufacturer

Name : **PATHKITS HEALTHCARE PRIVATE LIMITED**
Address : **28, 29, ELECTRONIC CITY, SECTOR-18, GURGAON-122001, HARYANA, INDIA**
Product: : **DEALS IN IN VITRO DIAGNOSTIC DEVICES, RNA/DNA ISOLATION KITS, RT PCR KITS, VIRAL TRANSPORT MEDIA, RAPID KITS FOR DIAGNOSTICS, BIO CHEMISTRY PRODUCTS, URINE STRIPS FOR DIAGNOSTICS, OTHER RELATED MEDICAL DIAGNOSTIC KITS & GENERAL HEALTH CHECKUP EQUIPMENTS**

The technical documentation / inspection / test results comply with the requirements of **Class-I Medical Device Directive 93/42/EEC**. Hence the manufacturer has issued a Declaration of Conformity according to test report and places the CE marking with his own Responsibility. The quality system has been assessed, approved and is subject to continuous surveillance according to the directives.

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.

Certificate Number: CE21020088

The validity of this certificate can be verified at www.ukicl.org.uk

Date of Certification: 11/02/2021
2nd Surveillance Due: 10/02/2023

1st Surveillance Due: 10/02/2022
Expire/ Re-Certificate Due: 10/02/2024




Authorise Signatory