

# Certificate of Compliance



We hereby declare that the technical file of product complied with the requirement **Medical Devices Regulation (EU) 2017/745**

**Certificate No.: CE-5725**

**Name : YUVRAJ BIOBIZ INCUBATOR INDIA PRIVATE LIMITED**

**Address : W2, WATER WORKS ROAD, THIRUVIKA INDUSTRIAL ESTATE, GUINDY,  
CHENNAI – 600032, TAMILNADU, INDIA**

**Product : RAPITEST - HIV 1/2, RAPITEST - DENGUE NS1, RAPITEST - DENGUE COMBO (NS1 AND  
IGG/IGM), RAPITEST – SYPHILIS DEVICE, RAPITEST - MALARIA PF/PV**

**Complies with the requirements applicable to it**

The quality system file has been assessed, approved and is subject to continuous surveillance according to the Council Directive on **Medical Devices Regulation (EU) 2017/745**

**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. 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.eurocertverify.com](http://www.eurocertverify.com)**

Date of Certification	1st June 2024
1st Surveillance Audit Due	31st May 2025
2nd Surveillance Audit Due	31st May 2026
Certificate Expiry	31st May 2027

  
**Authorised Signatory**



This certificate is the property of Eurocert Inspection Limited and shall be returned immediately on request.  
International House, 10 Churchill Way, Cardiff, United Kingdom, CF10 2HE  
Website:- [www.eurocertverify.com](http://www.eurocertverify.com), Email:- [info@eurocertverify.com](mailto:info@eurocertverify.com)  
Company No. 11956886

# Certificate of Compliance



We hereby declare that the technical file of product complied with the requirement **Medical Devices Regulation (EU) 2017/745**

**Certificate No.: CE-5726**

**Name : YUVRAJ BIOBIZ INCUBATOR INDIA PRIVATE LIMITED**

**Address : W2, WATER WORKS ROAD, THIRUVIKA INDUSTRIAL ESTATE, GUINDY,  
CHENNAI – 600032, TAMILNADU, INDIA**

**Product : TESTOOL - DILUENT FOR STOOL SPECIMEN PREPARATION FOR STOOL ROUTINE  
EXAMINATION, RAPITEST - HCG - ONE STEP URINE PREGNANCY TEST, RAPITEST – HBSAG,  
RAPITEST – HCV, RAPITEST – COVID19 AG TEST**

**Complies with the requirements applicable to it**

The quality system file has been assessed, approved and is subject to continuous surveillance according to the Council Directive on **Medical Devices Regulation (EU) 2017/745**

**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
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Company No. 11956886