CERTIFICATE Zertifikat Certifikát ΠΙΣΤΟΠΟΙΗΤΙΚΟ Tödistus Сертификат

CERTIFICATE OF COMPLIANCE

No: CE -1903

Certificate Holder	**YUVRAJ BIOBIZ INCUBATOR INDIA PRIVATE LIMITED** W-2, Water Works Road, Thiru Vi Ka Industrial Estate, Guindy, Chennai – 600 032, Tamil Nadu, India.
Product(s)	HCG Syphilis Malaria Pf/Pan Ag Malaria Pf/Pv Ag Dengue NS1 Dengue IgG/IgM Dengue NS1/IgG/IgM Cardiac Troponin Typhoid IgG/IgM Stool Testing Reagent
Brand Name	RAPITEST, TESTOOL
Classification	General (Devices other than listed in Annex II)
Verification to:	Standard: EN ISO 13485:2016, EN ISO 15223-1:2016, EN ISO 18113-1:2011, EN ISO 14971:2012, EN 13612:2002, EN 13975:2003, EN 13532:2002 Related to Directive: 98/79/EC (In vitro diagnostic medical devices) As per Annex III

Issue date: 23 JULY 2021

Expiry date: 22 JULY 2022

Remark: Based on the successful review of technical construction file documentation of the above mentioned products, UCAS confirms manufacturer ability to keep permanently the required safety and quality level. The manufacturer is obligated to assure that all medical devices of the respective models conform to the type approved by this certificate. The certificate remains valid until the manufacturing conditions and quality system as per the technical documentation are maintained or relevant legislation are changed. The product liability rests with the manufacturer or his representative in accordance with applicable Directive and Standard, after fulfilling the relevant EU legislation requirements, the manufacturer shall affix CE mark to each medical device of the above reference models.

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Authorised Signatory

UNIVERSAL CERTIFICATION ASSESSMENT SERVICES
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CERTIFICATE Zertifikat Certifikát ΠΙΣΤΟΠΟΙΗΤΙΚΌ Tõdistus Сертификат

CERTIFICATE OF COMPLIANCE

No: CE -1904

Certificate Holder	**YUVRAJ BIOBIZ INCUBATOR INDIA PRIVATE LIMITED** W-2, Water Works Road, Thiru Vi Ka Industrial Estate, Guindy, Chennai – 600 032, Tamil Nadu, India.
Product(s)	Covid-19 Ag
Brand Name	RAPITEST
Classification	General (Devices other than listed in Annex II)
Verification to:	Standard: EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 15223-1:2016, EN 1041:2008, EN ISO 18113-1:2011, EN 13612:2002, EN 13975:2003, EN 13532:2002
	Related to Directive: 98/79/EC (In vitro diagnostic medical devices) As per Annex III

Issue date: 06 AUGUST 2021

Expiry date: 05 AUGUST 2022

Remark: Based on the successful review of technical construction file documentation of the above mentioned products, UCAS confirms manufacturer ability to keep permanently the required safety and quality level. The manufacturer is obligated to assure that all medical devices of the respective models conform to the type approved by this certificate. The certificate remains valid until the manufacturing conditions and quality system as per the technical documentation are maintained or relevant legislation are changed. The product liability rests with the manufacturer or his representative in accordance with applicable Directive and Standard, after fulfilling the relevant EU legislation requirements, the manufacturer shall affix CE mark to each medical device of the above reference models.

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