



# Certificate of Compliance

This is to certify that the technical documentation for the

**Product Reference:** Immunochromatographic  
Rapid Cards & Strip

**Product Discription:** as per Annexure

Applicant:

**NuLife**

D - 22 / 118, Sector - 7, Noida - 201301 (Uttar Pradesh), India.

Complies with the applicable requirements of **Medical Devices Directive 93/42/EEC**  
**and 2007/47/EC Directive**

The technical documentation / inspection / test results comply with the requirements of **Medical Devices Directive** hence manufacturer's declaration of conformity according to above directive is accepted. **NuLife** can place the CE marking as per laid down regulations on the products mentioned as above.

Datum Van Publicatie / Date of Issue : 05/10/2019  
Vervaldatum / Date of Expiry : 04/10/2022  
Ist Annual surveillance audit due on : 04/09/2020  
IInd Annual surveillance audit due on : 04/09/2021

Director (Certification)

## Royal Stancert B.V.

Feitelijke Beoordelingen - Wereldwijde Beoordelingen  
Certificaat Nummer / Certificate No. : CE-BV-1910-1963

Regd. Office - Joop Geesinkweg 701, 1114 AB Amsterdam, The Netherlands..  
(KvK-Nummer 71431802 / RSIN 858713159 - Rechtsvorm - Besloten Vennootschap).

This certificate remains the property of Royal Stancert B.V. and must be returned whenever demanded. The validity of this certificate can be verified at <http://www.royalstancert.nl>. Royal Stancert B.V. is an independent system, product and personal assessment body accredited by Global Euro Accreditation Centre, Georgia. (GCIN - 654). Email: [info@royalstancert.nl](mailto:info@royalstancert.nl)



191963



PAC-GEAC-1506-299



# Certificate of Registration

**Annexure to CE Conformity Certificate No. CE-BV-1910-1963**

**Products covered by this certificate:**

S.No	Product Name
1	AbChek Malaria Pf (HRP2)/Pv (pLDH) Antigen Rapid Test Kit
2	AbChek Malaria Pf (HRP2)/PAN(pLDH) Antigen Rapid Test Kit
3	AbChek Dengue NS1 Antigen Rapid Test Kit
4	AbChek Dengue Combo Rapid Test Kit (Dengue NS1 Ag+IgG/IgM Ab)
	AbChek Dengue IgG/IgM Antibody Rapid Test Kit
5	AbChek HIV Rapid Test Kit
6	AbChek HBsAg Rapid Test Kit
7	AbChek HCV Rapid Test Kit
8	AbChek Syphilis Rapid Test Kit (Cassette)
9	AbChek Syphilis Rapid Test Kit (Dipsticks)
10	HCG Rapid Test Kit (Dipsticks)
	HCG Rapid Test Kit (Cassette)
11	UriPrep (Glucose + Protein)
12	Chikungunya Igm Rapid Test Kit
13	Typhoid IgG/IgM Rapid test kit
14	HAV Rapid test kit
15	HEV rapid test kit

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