



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07



Product Service

EC Certificate

EC Design-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (4)
(List A)

No. V7 052591 0011 Rev. 00

Manufacturer:

**Shanghai Kehua Bio-engineering
Co., Ltd.**

1189 North Qinzhou Road
200233 Shanghai
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

DIAnearing Diagnostics Engineering & Research GmbH
Friedrichstrasse 26, 69221 Heidelberg-Dossenheim, GERMANY

Product:

**Reagents for determination of infection markers
for HIV-1 / HIV-2: Anti-HIV-1 / HIV-2 Rapid Tests**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with IVDD Annex IV (4). The design of the devices conforms to the requirements of this Directive. See also notes overleaf.

Report No.:

713081683

Valid from:

2018-09-12

Valid until:

2023-09-11

Date,

2018-09-12

Stefan Preiß



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No. V7 052591 0011 Rev. 00

Model(s):

Diagnostic Kit for HIV (1+2) antibody
(Colloidal Gold) V2

Facility(ies):

Shanghai Kehua Bio-engineering Co., Ltd.
1189 North Qinzhou Road, 200233 Shanghai, PEOPLE'S
REPUBLIC OF CHINA

Parameters:

Brand Name:

Diagnostic Kit for HIV (1+2) antibody (Colloidal Gold) V2

Cat.no.:

KH-R-02-CE, R-401-1-C-CE, R-401-25-C-1-CE