



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

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 063963 0008 Rev. 00

Manufacturer:

Jei Daniel (JD) Biotech Corp.

A201, Building 1, No.69, Hua Yang Road
250100 Jinan, Shandong
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

**Shanghai International Holding Corp. GmbH
(Europe)**

Eiffestraße 80, 20537 Hamburg, GERMANY

Product

Self tests

Category(ies):

Rapid tests for self testing of infectious diseases

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. See also notes overleaf.

Report no.:

BJ2093707

Valid from:

2020-09-04

Valid until:

2025-09-03

Date,

2020-08-16

Stefan Preiß



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Model(s):

Candida Albicans (Yeast) Antigen Rapid Test Kit,
Gardnerella Vaginalis Antigen Rapid Test Kit,
Trichomonas Vaginalis Antigen Rapid Test Kit,
Trichomonas V./ C.albs(yeast) / Gardnerella V.Ag Test
Triple(3 in 1) STD panel Rapid Test Kit, Candida Albs
(Yeast) / Gardnerella Vaginalis Antigen Combo (2/1)
Rapid Test Kit, Fecal Occult Blood (FOB) Rapid Test,
FSH Menopasure Rapid Test Kit for Home Usage, Hcg
Pregnancy Rapid Test Kits for Home Usage, H. Pylori
Antigen Detection, LH Ovulation Rapid Test Kts for
Home Usage, Trichomonas V./ C.albs (yeast) Ag Test
Combo (2 in 1) STI panel Rapid Test Kit, Standard
Sexual Health Self Rapid Urine Test (7 in 1).

Facility(ies):

Jei Daniel (JD) Biotech Corp.
A201, Building 1, No.69, Hua Yang Road, 250100 Jinan,
Shandong, PEOPLE'S REPUBLIC OF CHINA