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 Category(ies):
Self tests

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.: BJ1893707

Valid from: 2018-09-04
Valid until: 2023-09-03

Date, 2018-08-16

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

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

TÜV SÜD 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

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, Trichomoans V./ C.albs (yeast) Ag Test Combo (2 in 1) STI panel Rapid Test Kit,Trichomonas V /Gardnerella V Antigen Combo (2/1) Rapid Test Kit.

Facility(ies):

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

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

A4 / 07.17