



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 058008 0030 Rev. 02

Manufacturer:

GUANGZHOU WONFEO BIOTECH CO., LTD.

No. 8 Lizhishan Road, Science City
Luogang District
510663 Guangzhou
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): **Products for determination of tumor markers (PSA)**
Chlamydia, Blood Glucose and self testing products

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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V1_058008_0030_Rev.02

Report no.: SH2114101

Valid from: 2022-03-18

Valid until: 2025-05-26

Date, 2022-03-18

Christoph Dicks
Head of Certification/Notified Body



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Model(s):

One Step Prostate Specific Antigen (PSA) Serum/Plasma Test, One Step Prostate Specific Antigen (PSA) Whole Blood/Serum/Plasma Test, One Step FSH Urine Test, Blood Glucose Monitoring System for Self Testing, One Step Strep A Swab Test, One Step Chlamydia Swab Test, One Step Influenza A Test, One Step Influenza B Test, One Step Influenza A&B Test, Digital Pregnancy Test, PSA Rapid Quantitative Test, Sperm Concentration Test, One Step Fecal Occult Blood (FOB) Test , Prostate Specific Antigen Control, Diagnostic kit for Human IgM Antibody of Chlamydia Pneumoniae(Immunochemical Assay), Digital OvulationTest, FPSA (Free Prostate Specific Antigen) Quantitative Rapid Test, Digital Pregnancy Test with Conception Indicator, One Step Ovulation Urine Test, One Step HCG Urine Test

Facility(ies):

GUANGZHOU WONDFO BIOTECH CO., LTD.
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Guangzhou, PEOPLE'S REPUBLIC OF CHINA

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