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 058008 0030 Rev. 00

Manufacturer: **GUANGZHOU WONDFO 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. See also notes overleaf.

Report no.: SH1914117

Valid from: 2019-10-15

Valid until: 2023-04-08

Date, 2019-09-19

Stefan Preiß
Head of Certification/Notified Body

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

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

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

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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 058008 0030 Rev. 00

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

.

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