



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 10 09 58008 008

Manufacturer: **GUANGZHOU WONDFO BIOTECH CO., LTD.**

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

EC-Representative: **Qarad b.v.b.a.
European Regulatory Services**

Volmolenheide 13
2400 Mol
BELGIUM

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.: SH1014106

Valid until: 2013-04-08

Hans-Heiner Junker

Date, 2010-12-28



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

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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 10 09 58008 008

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
(REF: WM801W Series, include
Blood Glucose Meter, Test Strip and Control
Solution),
One Step Strep A Swab Test,
One Step Chamydia Swab Test,
One Step Influenza A Test,
One Step Influenza B Test,
One Step Influenza A&B Test,
Digital Pregnancy Test
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Products as specified in the attachment

Facility(ies):

GUANGZHOU WONDFO BIOTECH CO., LTD.
No. 8 Lizhishan Road, Science City, Luogang District, 510663
Guangzhou, PEOPLE'S REPUBLIC OF CHINA

GUANGZHOU WONDFO BIOTECH CO., LTD.
South China University of Technology, 510641 Tianhe, PEOPLE'S
REPUBLIC OF CHINA



Attachment for Certificate no V1 10 09 58008 008

Supplement 001 dated 2010-12-28

Product Service

For the product(s)/product category (ies):

List B Product:

Prostate Specific Antigen (PSA) Test

Chamydia Test

Blood Glucose Monitoring System for Self Testing

Self Testing Product:

FSH Urine Test

Strep A Test

Influenza Test

Pregnancy Test

München, CRT 2, 2010-12-28

Hans-Heiner Junker

