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

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. 02

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. 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

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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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. 02

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

GUANGZHOU WONDFO BIOTECH CO., LTD.
501 Room,5F Self-edited Building 1, No.8 Lianhuayan Road, Huangpu District, 510663 Guangzhou, PEOPLE'S REPUBLIC OF CHINA

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

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Wondfo

EC DECLARATION OF CONFORMITY

According to the *In Vitro* Diagnostic Medical Device Directive 98/79/EC

Document No.: DOC-W039(2)-01
Version: 01

Manufacturer:	**Guangzhou Wondfo Biotech Co., Ltd.**
Address:	No.8, Lizhishan Road, Science City, Luogang District, 510663, Guangzhou, P.R. China
EC Authorised Representative:	Qarad BV
Address:	Cipalstraat 3, 2440 Geel, Belgium

***In Vitro* Diagnostic Medical Device(s):**

Product Name:	One Step Strep A Swab Test
Cat. No.:	W039P0001, W39-CH, W39-SH
IVDD Classification:	Non-Annex II, for self-testing

This declaration of conformity is issued under the sole responsibility of the manufacturer that the above product(s) meet(s) the provisions of the European Directive 98/79/EC for *In Vitro* Diagnostic Medical Devices.

The following (harmonized) standards have been applied:

EN ISO 13485:2016	EN ISO 18113-1:2011	EN ISO 18113-4:2011
EN ISO 14971:2012	EN ISO 15223-1:2016	EN 13612:2002
EN 13532:2002	EN ISO 23640:2015	EN 13641:2002
EN 62366-1:2015		

The conformity with the requirements of the Directive has been assessed following the procedure(s) outlined in the following annexes of the Directive: **Annex IV, excluding 4 and 6**

Notified Body (if consulted):	**TÜV SÜD Product Service GmbH (NB # 0123)**
Address:	Ridlerstraße 65, D-80339 München
EC Certificate(s):	V1 058008 0030 Rev.02
Expiry date of the Certificate(s):	2025-05-26
Signature of manufacturer	
(Name and function):	Bin Yang, Senior Vice President of Regulatory Affairs
Place and date of issue:	Guangzhou, P.R. China, May 23, 2022

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

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 058008 0025 Rev. 03

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

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate: **Design and Development, Production, Distribution, Installation and Service of In Vitro Diagnostics for the Detection of Fertility, Pregnancy, Infectious Diseases, Drugs of Abuse, Tumor Markers, Cardiac Markers, Diabetes Markers, Renal Injury Markers, Autoimmune Diseases, Infection, Inflammation, Coagulation Factors, Blood Gas Markers and Related Instruments, Sperm Concentration Tests, Fluorescence Immunoassay Systems, Blood Glucose Monitoring Systems, Control Materials for Tumor Markers, Biochemical Reagents and Instruments**

The Certification Body of TÜV SÜD Product Service GmbH certif
ies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). 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:Q5 058008 0025 Rev. 03

Report No.:	SH2114101
Valid from:	2022-03-18
Valid until:	2024-01-31

Date, 2022-03-18

Christoph Dicks
Head of Certification/Notified Body

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DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 058008 0025 Rev. 03

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

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

Design and Development, Distribution of In Vitro Diagnostics for the Detection of Fertility, Pregnancy, Infectious Diseases, Drugs of Abuse, Tumor Markers, Cardiac Markers, Diabetes Markers, Renal Injury Markers, Autoimmune Diseases, Infection, Inflammation, Coagulation Factors, Blood Gas Markers and Related Instruments, Sperm Concentration Tests, Fluorescence Immunoassay Systems, Blood Glucose Monitoring Systems, Control Materials for Tumor Markers, Biochemical Reagents and Instruments

Production of In Vitro Diagnostic Reagents for the Detection of Fertility, Pregnancy, Infectious Diseases, Drugs of Abuse, Tumor Markers, Cardiac Markers, Diabetes Markers, Renal Injury Markers, Autoimmune Diseases, Infection, Inflammation, Coagulation Factors, Blood Gas Markers, Sperm Concentration, Control Materials for Tumor Markers, Biochemical Reagents

GUANGZHOU WONDFO BIOTECH CO., LTD.
501 Room,5F Self-edited Building 1, No.8 Lianhuayan Road, Huangpu District, 510663 Guangzhou, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production, Installation and Service of In Vitro Diagnostic Instruments for Blood Gas, Fluorescence Immunoassay, Blood Glucose and Biochemical

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Puritan
Quality since 1919

CERTIFICATE OF COMPLIANCE AND STERILITY
March 5, 2024

Customer: TEO Sp. Zo.o. Sp.k.

Purchase Order #: N/A

Work Order #: N/A

Lot #: A679

Quantity: N/A

Expiration Date: 2028-09-01

Puritan Medical Products Part #: 25-806 1PRB

Products Description: Sterile, rayon 6” tipped applicator, plastic shaft.
Pack: 10/100/1 per pkg

Puritan Medical Products Company LLC certifies that the above product was produced with the specified materials and in compliance with our manufacturing and sterility specifications. Sterilization compliant with ANSI/AAMI ISO 11135

PURITAN MEDICAL PRODUCTS COMPANY LLC

Renee Hasting
Quality Assurance Specialist

RSH

Puritan Medical Products Company
31 School Street, P.O. Box 149, Guilford, ME 04443 USA
207.876.3311 • 800.321.2313 puritanmedproducts.com

PURITAN MEDICAL PRODUCTS COMPANY LLC

Safety Data Sheet

Rev. 02 April 3, 2015

1. Product and company identification

Product name: Rayon Tipped Applicator with Polystyrene Handle

Product number: 806-PR (25-806 1PR & 25-806 2PR)

Company identification:
Puritan Medical Products Company LLC
P.O. Box 149, 31 School Street
Guilford, Maine 04443-0149 U.S.A.

Contact numbers:
Tel: +1 207-876-3311
Fax: + 1 207-876-3130

2. Hazards identification

Skin contact:	None
Hazardous ingredients:	None

3. Composition/information on ingredients

Product consists of a rayon tip with a polystyrene handle. Non hazardous materials.

4. First-aid measures

Skin contact:	N/A
Eye contact:	N/A
Inhalation:	N/A
Swallowing:	Immediately call a doctor.

5. Fire-fighting measures

Extinguishing media:	CO_2, Extinguishing powder or water spray. Fight larger fires with water or alcohol resistant foam.
Protective Equipement:	No protective equipment required

6. Accidental release measures

Personal precautions:	No personal protective equipment required.
Environmental precautions:	N/A
Methods for cleaning up:	N/A

7. Handling and storage

Handling:	No special handling procedures required
Storage:	Store away from oxidizing agents Store in dry conditions.

8. Exposure controls/personal protection

Respiratory protection:	N/A
Hand protection:	N/A
Eye protection:	N/A
Skin and body protection:	N/A

9. Physical and chemical properties	
Odor:	Odorless
pH:	Not applicable
Density:	Not determined
Boiling point, °C:	Not determined
Melting point, °C	Not determined
Flash point, °C:	Not applicable
Solubility:	Insoluble
10. Stability and reactivity	
Materials and conditions to avoid:	No decomposition if used according to specifications
Hazardous decomposition products:	No dangerous decomposition products known
11. Toxicology information	
Acute effects:	None
Chronic effects:	None
Exposure limits:	None
Carcinogenicity (to humans):	None
12. Ecological Information	
Ecology:	The ecological effects have not been thoroughly investigated, but currently none have been identified. Not known to be hazardous to water.
13. Disposal considerations	
Recommendation:	Dispose used devices that have been processed with human samples as if biohazardous. Wastes containing these products should be disposed of in a manner consistant with state, federal, and local regulations.
14. Transport information	
No special transportation needed. Non-hazardous material.	
15. Regulatory information	
Not classified as a hazardous material.	
16. Other information	
Puritan Medical Products Company LLC provides the information in this document in good faith and believes the information to be accurate. The chemical, physical and toxicological properties of this product have not been thoroughly investigated. It is the responsibility of the buyer to research and understand safe methods of handling, storing, and disposal of this product. Puritan Medical makes no warranty with respect to such information and assumes no liability for any loss or injury, which may result from the use of this information. It is the buyers responsibility to comply with local, state and federal regulations concerning use and disposal of this product.	