



Product Service

Certificate

No. Q5 086238 0004 Rev. 02

Holder of Certificate:

**Jiangsu Bioperfectus
Technologies Co., Ltd.**

3rd and 4th floors of Building A(G19)
4th floor of Building F(G14)
Ground floor of Building G20, Shuaiyu Village, Fuye village
Sixiang town, Taizhou National Medical
Hi-tech Development Zone
225300 Taizhou, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

**Design and Development, Production and Distribution of
Automatic Detection Workstation of Vaginitis, Diagnostic
Kits for DNA or RNA Pathogens, Test Kits for Biochemical
Factors of the Secretions by Dry Chemoenzymatic Method,
Nucleic Acid Extraction System, Rapid Tests based on the
Colloidal Gold Chromatography Technology, Nucleic Acid
Extraction Kit**

The Certification Body of TÜV SÜD Product Service GmbH certifies 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 086238 0004 Rev. 02

Report No.:

SH2080001

Valid from:

2021-12-02

Valid until:

2022-12-04

Date,

2021-12-02

Christoph Dicks

Head of Certification/Notified Body

Certificate

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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):

Jiangsu Bioperfectus Technologies Co., Ltd.
3rd and 4th floors of Building A(G19), 4th floor of Building
F(G14), Ground floor of Building G20, Shuaiyu Village, Fuye
village, Sixiang town, Taizhou National Medical, Hi-tech
Development Zone, 225300 Taizhou, Jiangsu, PEOPLE'S
REPUBLIC OF CHINA

Design and Development of Test Kits for Biochemical Factors of
the Secretions by Dry Chemoenzymatic Method

Production of Diagnostic Kits for DNA or RNA Pathogens, Test
Kits for Biochemical Factors of the Secretions by Dry
Chemoenzymatic Method, Rapid Tests based on the Colloidal
Gold Chromatography Technology

Distribution of Automatic Detection Workstation of Vaginitis,
Diagnostic Kits for DNA or RNA Pathogens, Test Kits for
Biochemical Factors of the Secretions by Dry Chemoenzymatic
Method, Nucleic Acid Extraction System, Rapid Tests based on
the Colloidal Gold Chromatography Technology, Nucleic Acid
Extraction Kit

Jiangsu Bioperfectus Technologies Co., Ltd.
Room 102 and 2th Floor, Bldg. 10A, 188 Xinjunhuan Rd.,
Caohejing Pujiang Hi-tech Park, 201114 Shanghai, PEOPLE'S
REPUBLIC OF CHINA

Design and Development of Automatic Detection Workstation of
Vaginitis, Diagnostic Kits for DNA or RNA Pathogens, Nucleic Acid
Extraction System, Rapid Tests based on the Colloidal Gold
Chromatography Technology, Nucleic Acid Extraction Kit

Jiangsu Bioperfectus Technologies Co., Ltd.
1-2 Floor, Building 7-2, Phase 6, Pharmaceutical Park, 225300
Taizhou city, Jiangsu, PEOPLE'S REPUBLIC OF CHINA

Production of Nucleic Acid Extraction Kit, Nucleic Acid Extraction
System, Automatic Detection Workstation of Vaginitis