





Certificate

No. Q5 086238 0004 Rev. 01

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:



Design and Development, Production and Distribution Scope of Certificate:

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

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). See also notes overleaf.

Report No.: SH1980007

Valid from: 2019-12-05 Valid until: 2022-12-04

2019-11-20 Date.

Christoph Dicks

Head of Certification/Notified Body

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EN ISO 13485:2016 Applied Standard(s):

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

Jiangsu Bioperfectus Technologies Co., Ltd.

4th floor, Bldg. 8A, 188 Xinjunhuan Rd., Caohejing Pujiang Hi-tech Park, 201114 Shanghai, PEOPLE'S REPUBLIC OF CHINA

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