



Product Service

Certificate

No. Q5 092305 0001 Rev. 00

Holder of Certificate: **Zhejiang Orient Gene Biotech Co., Ltd.**
3787#, East Yangguang Avenue, Dipu Street Anji
313300 Huzhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: Design and Development, Production and Distribution of In Vitro Diagnostic Reagents for Cardiac Diseases, Infectious Diseases, Oncology and for Biochemistry as well as Rapid Tests for Fertility, Rapid Tests for Drugs of Abuse, Chlamydia Trachomatis Antigen, Toxoplasma gondii(Toxo) IgG/IgM, Toxoplasma gondii(Toxo) IgG, Toxoplasma gondii(Toxo) IgM, Digital Pregnancy Tests for Self-testing, and Distribution of Urine Analyzer as well

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_092305_0001_Rev_00

Report No.: SH2098801

Valid from: 2021-03-17

Valid until: 2024-03-16

Date, 2021-03-03

Christoph Dicks
Head of Certification/Notified Body





Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



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No. Q5 092305 0001 Rev. 00

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): Zhejiang Orient Gene Biotech Co., Ltd.
3787#, East Yangguang Avenue, Dipu Street Anji, 313300
Huzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate





浙江东方基因生物制品股份有限公司
Zhejiang Orient Gene Biotech Co., LTD



CE-DOC-OG060
Version 2.0

EC Declaration of Conformity

In accordance with Directive 98/79/EC

Legal Manufacturer: *Zhejiang Orient Gene Biotech Co., Ltd*

Legal Manufacturer Address: *3787#, East Yangguang Avenue, Dipu Street,
Anji 313300, Huzhou, Zhejiang, China*

Declares, that the products
Product Name and Model(s)

Fecal Occult Blood Rapid Test Strip (Feces)	GEFOB-601b
Fecal Occult Blood Rapid Test Cassette (Feces)	GEFOB-602b

Classification: *Other*
Conformity assessment route: *Annex III (EC DECLARATION OF CONFORMITY)*

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint

EC Representative's Name: CMC Medical Devices & Drugs S.L

EC Representative's Address: C/Horacio Lengo Nº 18, CP 29006, Málaga, Spain

to act as our European Authorized Representative as defined in the aforementioned Directive.

I, the undersigned, hereby declare that the medical devices specified above conform with the directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements

Date Signed: May 20, 2022

Name of authorized signatory: Joyce Pang
Position held in the company: Vice-President



浙江东方基因生物制品有限公司
Zhejiang Orient Gene Biotech Co.,LTD



CE-DOC-OG040
version 1.0

EC Declaration of Conformity

In accordance with Directive 98/79/EC

Legal Manufacturer: Zhejiang Orient Gene Biotech Co., Ltd

Legal Manufacturer Address: 3787#, East Yangguang Avenue, Dipu Street,
Anji 313300, Huzhou, Zhejiang, China

Declares, that the products
Product Name and Model(s)

<i>H. pylori</i> Ab Rapid Test Strip (Whole blood/Serum/Plasma)	GCHP-401a
<i>H. pylori</i> Ab Rapid Test Cassette (Whole blood/Serum/Plasma)	GCHP-402a

Classification : Other
Conformity assessment route: Annex III (EC DECLARATION OF CONFORMITY)

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint

EC Representative's Name : Shanghai International Holding Corp. GmbH (Europe)

EC Representative's Address: Eiffestrasse 80, 20537 Hamburg, Germany

to act as our European Authorized Representative as defined in the aforementioned Directive.

I, the undersigned, hereby declare that the medical devices specified above conform with the directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements

Date Signed: November. 28th, 2017

Name of authorized signatory: Joyce Pang
Position held in the company: Vice-President