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 095123 0008 Rev. 04

Manufacturer:

Hangzhou AllTest Biotech Co., Ltd.
550#, Yinhai Street
Hangzhou Economic and Technological Development Area
310018 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): **Products for determination of infection markers tumor markers and products for self testing**

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 095123 0008 Rev. 04

Report no.: SH221064A02

Valid from: 2022-04-05
Valid until: 2025-05-26

Date, 2022-04-05

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 095123 0008 Rev. 04

Model(s):

Toxo IgG/IgM Rapid Test,
Rubella IgM Rapid Test,
CMV IgM Rapid Test,
ToRCH IgM Combo Rapid Test,
PSA Rapid Test,
PSA Qualitative Rapid Test,
Chlamydia Rapid Test,
Sperm Concentration Rapid Test,
SP-10 Male Fertility Rapid Test,
hCG Rapid Test,
Digital hCG Pregnancy Test
LH Rapid Test,
FSH Rapid Test,
Vaginal pH Rapid Test,
Ferritin Rapid Test,
TSH Rapid Test,
H.pylori Rapid Test,
Urinary Tract Infections Test,
FOB Rapid Test,
Vitamin D Rapid Test

Facility(ies):

Hangzhou AllTest Biotech Co., Ltd.
550#, Yinhai Street, Hangzhou Economic and Technological Development Area, 310018 Hangzhou, PEOPLE'S REPUBLIC OF CHINA

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

Product Service

Confirmation Statement on validity of EC Certificate (IVDD)

pursuant to Directive 98/79/EC concerning in vitro diagnostic medical devices

No. VCQ 095123 0013 Rev. 00

Manufacturer:

Hangzhou AllTest Biotech Co., Ltd.
550#, Yinhai Street
Hangzhou Economic and Technological Development Area
310018 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

This Confirmation Statement is only valid in combination with the following EC Certificate (IVDD):

V1 095123 0008 Rev. 04

This Confirmation Statement confirms the validity of the aforementioned EC Certificate (IVDD). It considers clarification of scope statements, scope reductions and changes to the manufacturer data initiated 26 May 2022 or later.
The conditions laid down in Article 110 (3) of Regulation (EU) 2017/746 on in vitro diagnostic medical devices for placing devices on the market and putting into service apply. For details and confirmation statement validity see: www.tuvsud.com/ps-cert?q=cert:VCQ 095123 0013 Rev. 00

Report No.: SH23106403

Valid until: 2025-05-26

Issue Date: 2023-09-20

Marta Carnielli
Head of Notified Body IVD

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Product Service

Confirmation Statement on validity of EC Certificate (IVDD)

pursuant to Directive 98/79/EC concerning in vitro diagnostic medical devices

No. VCQ 095123 0013 Rev. 00

Product Category(ies): Products for determination of infection markers tumor markers and products for self testing

Toxo IgG/IgM Rapid Test,
Rubella IgM Rapid Test,
CMV IgM Rapid Test,
ToRCH IgM Combo Rapid Test,
PSA Rapid Test,
PSA Qualitative Rapid Test,
Chlamydia Rapid Test,
Sperm Concentration Rapid Test,
SP-10 Male Fertility Rapid Test,
hCG Rapid Test,
Digital hCG Pregnancy Test
LH Rapid Test,
FSH Rapid Test,
Vaginal pH Rapid Test,
Ferritin Rapid Test,
TSH Rapid Test,
H.pylori Rapid Test,
Urinary Tract Infections Test,
FOB Rapid Test,
Vitamin D Rapid Test

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Product Service

Confirmation Statement on validity of EC Certificate (IVDD)

pursuant to Directive 98/79/EC concerning in vitro diagnostic medical devices

No. VCQ 095123 0013 Rev. 00

Description of Change:

Change of Facility(ies):

The facility(ies) of manufacturer has/have been changed

Old facility(ies):

Hangzhou AllTest Biotech Co., Ltd.
550#, Yinhai Street, Hangzhou Economic and Technological Development Area, 310018 Hangzhou, People's Republic of China

New facility(ies):

Hangzhou AllTest Biotech Co., Ltd.
550#, Yinhai Street, Hangzhou Economic and Technological Development Area, 310018 Hangzhou, People's Republic of China

Hangzhou AllTest Biotech Co., Ltd.
#383, Qiaoxin Road, Xiasha Street, Qiantang District, 310018 Hangzhou, Zhejiang, People's Republic of China

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