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. 01

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. See also notes overleaf.

Report no.: SH19106405

Valid from: 2019-11-11
Valid until: 2021-06-14

Date, 2019-11-11

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. 01

Model(s):

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