



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 17 06 95123 008

Manufacturer:

Hangzhou AllTest Biotech Co., Ltd.

550#, Yinhai Street
Hangzhou Economic and Technological Development Area
310018 Hangzhou
PEOPLE'S REPUBLIC OF CHINA



EC-Representative:

MedNet GmbH

Borkstrasse 10
48163 Muenster
GERMANY

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.:

SH17106403

Valid from:

2017-09-12

Valid until:

2021-06-14

Date, 2017-09-12

Stefan Preiß



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 2



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 17 06 95123 008

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**

Facility(ies):

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