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Zentralstelle der Länder
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bei Arzneimitteln und
Medizinprodukten
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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 093780 0004 Rev. 00

Manufacturer: **Qingdao Hightop Biotech Co., LTD**
No. 369 Hedong Road, Hi-Tech Industrial Development Zone
266112 Qingdao, Shandong
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_093780_0004_Rev_00

Report no.: BJ21099603

Valid from: 2021-11-16
Valid until: 2024-05-26

Date, 2021-11-12

Christoph Dicks
Head of Certification/Notified Body



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Model(s):

Ct Chlamydia Trachomatis Antigen Rapid Test Kit (Colloidal Gold), One Step HCG Urine Pregnancy Rapid Test Kit (Colloidal Gold), PSA Prostate Specific Antigen Rapid Test Kit (Colloidal Gold), CMV Cytomegalovirus Antibody IgM/IgG Rapid Test Kit (Colloidal Gold), CMV Cytomegalovirus Antibody IgM Rapid Test Kit (Colloidal Gold), CMV Cytomegalovirus Antibody IgG Rapid Test Kit (Colloidal Gold), RV Rubella Antibodies IgM/IgG Rapid Test Kit (Colloidal Gold), RV Rubella Antibodies IgM Rapid Test Kit (Colloidal Gold), RV Rubella Antibodies IgG Rapid Test Kit (Colloidal Gold), TOXO Toxoplasma Antibody IgM/IgG Rapid Test Kit (Colloidal Gold), TOXO Toxoplasma Antibody IgM Rapid Test Kit (Colloidal Gold), TOXO Toxoplasma Antibody IgG Rapid Test Kit (Colloidal Gold) and One Step LH Ovulation Rapid Test Kit (Colloidal Gold).

Facility(ies):

Qingdao Hightop Biotech Co., LTD
No. 369 Hedong Road, Hi-Tech Industrial Development Zone,
266112 Qingdao, Shandong, PEOPLES REPUBLIC OF CHINA