



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 15 04 42074 023

Manufacturer: **Acon Biotech (Hangzhou) Co., Ltd.**

No.210 Zhenzhong Road
West Lake District
310030 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: **Wellkang Ltd t/a Wellkang Tech Consulting**

Suite B, 29 Harley Street
London
W1G 9QR
UNITED KINGDOM

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.: SH1510618/SH15106EXT01

Valid from: 2015-07-15

Valid until: 2020-07-14



Date, 2015-06-11

Hans-Heiner Junker

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

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No. V1 15 04 42074 023

Model(s):

Total PSA EIA Test Kit
Toxoplasma IgG EIA Test Kit
Toxoplasma IgM EIA Test Kit
Rubella IgG EIA Test Kit
Rubella IgM EIA Test Kit
CMV IgG EIA Test Kit
CMV IgM EIA Test Kit
GlucoSure Blood Glucose Monitoring System
Cholesterol Monitoring System (CCM-111)
Cholesterol Monitoring System (CCM-101)
3-1 Lipid Panel Test Devices (CCS-114)
CHOL Total Cholesterol Test Devices (CCS-111)
TRIG Triglycerides Test Devices (CCS-112)
HDL High Density Lipoprotein Test Devices (CCS-113)
Cholesterol CTRL Control Devices
Urinalysis Reagent Strips (Urine)
UTI Urinary Tract Infection Test Strips
PT Coagulation Monitoring System (CCM-121)
On Call Plus Blood Glucose Monitoring System
On Call Advanced Blood Glucose Monitoring System
On Call EZII Blood Glucose Monitoring System
On Call Redi Blood Glucose Monitoring System
On Call Platinum Blood Glucose Monitoring System
On Call Resolve Blood Glucose Monitoring System
On Call Chosen Blood Glucose Monitoring System
On Call Vivid Blood Glucose Monitoring System (OGM-101)
On Call Simple Blood Glucose Monitoring System (OGM-111)
On Call Sharp Blood Glucose Monitoring System (OGM-121)
On Call Vivid Pal Blood Glucose Monitoring System
(OGM-102)
On Call GK Dual Blood Glucose & Ketone Monitoring System
(OGM-161)
On Call Plus II Blood Glucose Monitoring System (OGM-171)
On Call Extra Blood Glucose Monitoring System (OGM-191)
ROMO CHECK INSTA Blood Glucose Monitoring System
ROMO CHECK PLUS Blood Glucose Monitoring System

Facility(ies):

Acon Biotech (Hangzhou) Co., Ltd.
No.210 Zhenzhong Road, West Lake District, 310030
Hangzhou, PEOPLE'S REPUBLIC OF CHINA